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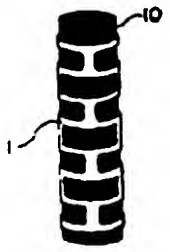
(54) Artificial tubular organ.

(57) An artificial tubular organ composed of a tubular supporting frame (1) made of a plastic material and provided on its at least one surface with a medical prosthetic material (10). The supporting frame (1) is composed of a plurality of ring portions (2) arranged on an axis (A), and a plural pairs of connecting portions (3) extending between neighboring two ring portions (2) to connect them each other, every other pairs of the connecting portions (3) being diametrically arranged on the ring portions (2), the remaining pairs of the connecting portions (3) being arranged such that the plane containing their center lines intersects at right angles with the plane containing the center lines of a pair of diametrically arranged connecting portions (3). The medical prosthetic material (10) may be a woven fabric, a knitted fabric, a nonwoven fabric, or a combination thereof. Preferred fabric comprises absorbable macromolecular yarns (11,13) and nonabsorbable macromolecular yarns (12,14).

Fig. 1



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The present invention relates to an artificial tubular organ and, more particularly, to on artificial tubular organ for use in substitution or reconstruction of tubular organs such as blood vessels, tracheae and esophagi.

BACKGROUND OF THE INVENTION

Recently, the development of artificial tubular organs has been energetically pushed forward to use them as a substitute for tubular organs such as blood vessels, tracheae and esophagi, and many clinical applications of such artificial organs have been reported in the medical field.

For the artificial tubular organs used as a substitute of tubular organs with a skeleton (cartilage) such as tracheae and bronchi, Belsey, R. has reported in British J. Surg. 39 200 (1950), clinical trials employing a stainless steel wire closely wound in the form of a helix and covered with a fascia, and Daniel, R.A et al have reported in Dis. Chest. 17 426 (1950) on experiments using a glass tube. These reports initiated the development of artificial tubular organs, and various investigations have been made on artificial tubular organs of a wide variety of materials.

In general, the requirements common to artificial tracheae are to have sufficient resistance to deformation, to cause no leakage of air, to be incorporated into organisms without causing significant inflammatory response. To meet these requirements, many studies have been conducted on materials for artificial tracheae, and their structure. The most artificial tracheae of the prior art are in the form of meshes or solid tubes, but the investigations in recent years are directed to artificial organs composed of supporting frame covered with a mesh such as woven fabrics or knitted goods.

In J. Thoracic & Cardovasc Surg. 72 525 (1976), Neville has stated the following six conditions required for an ideal artificial trachea.

(1) to be airtight to avoid leakage of expired air and inspired air;

(2) to have a suitable mechanical strength and resistance to deformation to avoid occlusion of trachea by pressure;

(3) to take with a organism,

(4) to be incorporated into the surrounding organisms with less inflammatory response;

(5) to prevent fibroblasts from passing therethrough as well as to prevent bacteria from making an invasion into the lumen; and

(6) to permit ingrowth of respiratory epithelia along the lumen.

However, there is no artificial trachea which satisfies all these conditions, especially, the conditions (3), (4) and (6) simultaneously.

For example, the artificial tracheae as shown in Figs. 9 and 10, known as an arched graft, involve a problem in the condition (3). Since such artificial tracheae generally comprise a mesh reinforced by a supporting frame 31 with a semicircular cross section shown in Fig. 9 or 10, they are poor in longitudinal extension and contraction. This causes abrasion or releasing from the surrounding tissue, resulting in failure in a take.

In Japanese patent national publication No. 2-501118, it has been proposed to use an artificial blood vessel comprising a medical prosthetic material of a tubular woven fabric constructed by alternately performing plain weave and twill weave. This artificial blood vessel is improved in softness and flexibility and may be used without performing coating of a coagulant. However, the softness is lost from the blood vessel by the adhesion with the surrounding tissues, so that the blood vessel cannot follow with the movement of the body, thus causing inflammation of the tissue.

Japanese patent lying-open No. 57-115250 discloses an artificial tubular organ coated with a blood coagulation factor XIII (or fibrin stabilizing factor), which is used as an artificial trachea to be implanted in a resected portion of the trachea invaded by the cancer or in a resected portion of bronchus affected with tumor. This artificial tubular organ causes no risks such as obstructive thrombus, formation of ulcer or stenochoria as a rate of organization just after implantation is improved by the blood coagulation factor XIII.

However, the woven fabric or knitted goods used as the medical prosthetic materials for artificial tubular organs have the following disadvantages. If the fabric has a low compactness, the prosthetic material possesses good softness, but it permits the internal air to pass therethrough and then intrudes into the tissue, causing inflammation due to microbism. If the prosthetic material is composed of a woven or knitted fabric of a compact construction, or of a fabric provided with a coating to give good airtightness and watertightness, the artificial tubular organ becomes rigid, does not fit to the surrounding tissue, prevents invasion of endotheliums, and causes disturbances in the surrounding tissue.

Commercially available artificial tubular organ comprises a silicone wire closely wound in the form of a helix and covered with a fabric to prevent the leakage of expired air or inspired air. In such an artificial

trachea, however, the granulation tissue is prevented from entering into the medical prosthetic material. Thus, the artificial trachea is prevented from incorporation into the surrounding tissue so that the migration of the artificial trachea occurs.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide an artificial tubular internal organ having high resistance to deformation and good airtightness, and capable of being incorporated into the tissue after implantation to provide good adhesion with the surrounding tissues.

The above and other objects of the present invention are achieved by providing an artificial tubular organ composed of a tubular supporting frame made of a plastic material and provided on its at least one surface with a medical prosthetic material, said supporting frame being composed of a plurality of ring portions arranged on an axis, and plural pairs of connecting portions extending between neighboring two ring portions to connect them each other, every other pairs of said connecting portions being diametrically arranged on said ring portions, the remaining pairs of said connecting portions being arranged such that the plane containing their center lines intersects at right angles with the plane containing the center lines of the diametrically arranged connecting portions in pair, said medical prosthetic material being composed of at least one fabric selected from the group consisting of woven fabrics, nonwoven fabrics, and knitted fabrics.

As a material for supporting frame, there may be used any biocompatible synthetic resins. Typical biocompatible synthetic resins include, without being limited to, olefin resins such as polyethylene, polypropylene; fluoroplastics such as polytetrafluoroethylene, ethylene-tetrafluoroethylene copolymers, polychlorotrifluoroethylene; and polyesters.

In a preferred embodiment, each pair of the connecting portions of the tubular supporting frame are diametrically arranged on the ring portions.

As a medical prosthetic material, there may be used any knwon fabrics including woven fabrics, nonwoven fabrics and knitted fabrics. It is, however, preferred to use a partially absorbable fabric comprising absorbable macromolecular yarns and nonabsorbable macromolecular yarns. Such a fabric may be used alone or in combination with any known fabrics comprising nonabsorbable macromolecular yarns or fibers. When a fabric comprising absorbable yarns is used in combination with a fabric made of nonabsorbable yarns, it is preferred that the former is sandwiched between the supporting frame and the latter.

The above partially absorbable woven fabric may be constructed by composite yarns composed of at least one absorbable macromolecular yarn and at least one nonabsorbable macromolecular yarn. Such composite yarns may be prepared by yarn doubling or twisting. Also, the fabric may be a union cloth or knitted fabric composed of absorbable macromolecular yarns and nonabsorbable macromolecular yarns.

The yarns for woven fabrics, nonwoven fabrics, knitted fabrics may be monofilament yarns or multifilament yarns. The most preferred yarns are false twist yarns as they improve airtightness and flexibility of the produced fabrics.

As a material for the nonabsorbable macromolecular yarns, there may be used those such as polyesters (e.g., polyethylene terephthalate); polyolefins (e.g., polyethylene polypropylene); polyamide resins (e.g., 6-nylon, 66-nylon); fluoroplastics (polytetrafluoroethylene, polyvinylidene fluoride); chlorine resins (e.g., polyvinylchloride, polyvinylidene chlorides); polyurethane resins; cellulose derivatives; or natural fibers. Among them it is preferred to use polyolefins since the granulation tissues firmly adhere to yarns of polyolefin fibers but never enter into the lumen of the supporting frame and thus provide no disturbance of the flow of blood or air.

As a material for the absorbable macromolecular yarns, there may be used those such as polylactide, polyglycolic acid, polyvinyl alcohol, polyacryl amide, polyvinyl pyrolidone, poly-γ-methyl-glutamade, polycaprolactone, polydioxanone and derivatives thereof, ethylene-carbon monoxide copolymers, cellulose derivatives or copolymers thereof, vinyl acetate-unsaturated carboxylic acid copolymers, and the like.

The above fabrics or composite yarns may be coated with a protein. Typical proteins includes, without being limited to collagen, gelatin, fibrinogen, globulin, and fibronectin. The protein coatings may be formed by immersing woven fabrics, non-woven fabrics or composite yarns in a protein solution and then rinsing them with water several times at room temperature.

The woven or nonwoven fabric comprises absorbable macromolecular yarns which are dissolved and absorbed in the organism to form openings or pores in the fabric after implantation. Preferably, the openings or pores to be formed in the fabric of the nonabsorbable macromolecular yarns after implantation have an average diameter of 110 µm and are present at least 20 % in the fabric.

The artificial tubular organ of the present invention is capable of being bent in any directions, back and

forth or left and right, because of a new construction of the tubular supporting frame. It is possible to make a discrimination in the bending angle of the artificial tubular organ between back and forth direction by suitably selecting location of the odd numbered or even numbered connecting portions in pair.

The provision of the connecting portions makes it possible to prevent the supporting frame from excess expansion in the axial direction, as well as to prevent aberration of the ring portions, thus making it possible to improve the resistance to deformation.

Further, the stitched joining the fabric with the supporting frame are limited in movement by the connecting portions, thus making it possible to avoid the deviation of the fabric from the given position on the tubular supporting frame.

Just after implantation of the artificial tubular organ, the medical prosthetic material of the woven, knitted, or nonwoven fabric prevents movement of substances such bacteria. With the lapse of time, however, the absorbable macromolecular yarns constituting the fabric are decomposed and absorbed in the organism so that numberless pores or openings are formed in the fabric. For this reason, the granulation tissues surrounding the artificial tubular organ enters into openings and grow up to form organism, while closing the openings of the fabric. As a results, the fabric with rough texture composed of the remaining nonabsorbable macromolecular yarns forms a dense composite with organism.

The above and other objects, features and advantages of the present invention will be further apparent from the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an artificial tubular organ embodying the present invention;
Fig. 2 is a perspective view of a supporting frame used in the artificial tubular organ of Fig. 1;
Fig. 3a is an enlarged perspective view of the supporting frame of Fig. 2;
Fig. 3b is an enlarged perspective view showing a modified form of the supporting frame of Fig. 2;
Fig. 4 is a fragmentary plan view of a medical prosthetic material composed of a woven fabric used in the artificial tubular organ of Fig. 1;
Fig. 5 is a perspective view of a supporting frame used in the artificial trachea according to the present invention;
Fig. 6 is a partially cut-away view of an artificial blood vessel according to the present invention;
Fig. 7 is a fragmentary plan view of a medical prosthetic material composed of a woven fabric used in the artificial tubular organ according to the present invention;
Fig. 8 is a fragmentary plan view of a medical prosthetic material composed of a nonwoven fabric used for an artificial tubular organ according to the present invention;
Fig. 9 is a diagrammatical perspective view of an artificial tubular organ of the prior art;
Fig. 10 is a diagrammatical perspective view of an another form of an artificial tubular organ of the prior art; and,
Fig. 11 is a diagrammatical perspective view of a further form of an artificial tubular organ of the prior art;

PREFERRED EMBODIMENT OF THE PRESENT INVENTION

Referring now to Fig. 1, there is shown an artificial tubular organ embodying the present invention, which comprises a tubular supporting frame (1) made of a plastic, and a medial prosthetic material (10) arranged in the lumen of the supporting frame (1) and joined thereto with several stitches.

The supporting frame (1) is made of a biocompatible synthetic resin in the form of a cylinder shape of a 5 to 30 mm length. This frame (1) comprises a plurality of ring portions (2) arranged on a common axis, and plural pairs of connecting portions extending between neighboring two ring portions to connect them each other.

The ring portions (2) constitute a side wall of the supporting frame (1) so that they are required to have a suitable compressive strength to prevent crushing of the artificial tubular organ, for example, artificial trachea after implantation into the organism. Although the compressive strength of the supporting frame varies with a thickness of the ring portions and a raw material used, the artificial trachea is generally designed such that it possesses the compressibility ranging from about 5 to 25 % when a load of 500 g is applied to the artificial trachea of 5 cm in length in the direction perpendicular to its axis. The ring portions may have any cross sections such as circular, square, or rectangular, but it is preferred that they have a rectangular cross section.

The connecting portions (3) are formed as an integral part of the supporting frame (1). A length of the connecting portions (3) is so determined that it is smaller than a radius of the ring portions (2). The

connecting portions may have any thickness as occasion demands, but it is preferred that they have a thickness substantially the same as that of the ring portions (2), taking account of the mechanical strength and easiness of molding.

The connecting portions (3) in pairs are diametrically arranged between the neighboring two ring portion (2) so that they are either above or below next connecting portion (3) but one. Thus, the connecting portions (3) in pair are symmetric with respect to the axis of the supporting frame (1), but odd numbered pairs of said connecting portions (3) are arranged such that the plane containing their center lines intersects at right angles with the plane containing the center lines of even numbered pairs of the connecting portions.

As fully illustrated in Fig. 3, the position of a pair of the connecting portions (3) with respect to an upper or lower pair of the connection portions (3) is determined such that a straight line (L_1), which connects the intersections of each of the connecting portions (3a, 3a') in pairs and the ring portion (2b), extends in the direction perpendicular to a straight line (L_2) which connects the intersections of each of the connecting portions (3b, 3b') in pair and the ring portion (2b). Also, each straight lines (L_1, L_2) intersect at right angles with the axis (A) of the supporting frame (1).

Fig. 4 shows the prosthetic material (10) composed of a woven fabric having a plain weave construction in which waft yarns (11, 12) pass alternately under and over warp yarns (13, 14) across the width of the fabric. One of the weft yarns, i.e., weft yarns (11) are absorbable macromolecular yarns, while the other weft yarns 12 are nonabsorbable macromolecular yarns. Similarly, one of the warp yarns 13 are absorbable macromolecular yarns, while the other warp yarns 14 are nonabsorbable macromolecular yarns.

In order to fix (immobilize) the implanted artificial tubular organ in the body, the artificial tubular organ is required to form pores in the textile after implantation so that granulation tissue enters into pores to form an inner structure rapidly. According to the present invention this is achieved by combined use of absorbable macromolecular yarns and nonabsorbable macromolecular yarns. The absorbable yarns are dissolved and absorbed in the body, thereby forming pores between the remaining nonabsorbable macromolecular yarns.

It is preferred that an average diameter of the produced pores is at least 110 µm, preferably, 300 to 1500 µm. Further, it is preferred that the pores of at least 110 µm present in the textile occupies at least 20 %, preferably, 40 to 70% of the surface area of the textile. If the average diameter of the pores is less than 110 µm, it is difficult for the granulation tissue to enter into pores between the fibers of the textile, causing failure in immobilization of the fiber structure in the body.

The above medical prosthetic material (10) or woven fabric is joined to the supporting frame (2) with several stitches. The stitching thread is composed of the same materials as materials of the fabric, i.e., absorbable macromolecular yarns and nonabsorbable macromolecular yarns.

When such an artificial tubular organ is implanted in the body, one of the constituents of the prosthetic material, i.e., absorbable macromolecular yarns are decomposed by breakage of their main chains of chemical structures and absorbed in the body to form openings or pores between non-absorbable macromolecular yarns, into which the granulation tissues enter into the openings or pores so that the artificial tubular organ firmly adheres to the surrounding tissues and is fixed thereto. Since the artificial tubular organ is required to have good airtightness and watertightness, the medical prosthetic material is constituted by a woven fabric with a high density. For this reason, the artificial tubular organ is initially stiffened, but it is then softened with the lapse of time as the absorbable macromolecular yarns are dissolved and absorbed in the body. This makes it possible to minimize an obstacle due to implantation as well as to avoid occurrence of inflammation.

In the above embodiment, all the pairs of the connecting portions (3) are diametrically arranged so that they are symmetric with respect to the axis of the supporting frame (1). However, this is not necessarily required. It is sufficient to make one of the straight lines (L_1, L_2) intersect perpendicularly to the axis (A) of the supporting frame (1).

Fig. 3b shows modification of a tubular supporting frame for use in the artificial tubular organ of the present invention. In this embodiment, one of the straight lines (L_1, L_2), for example, the straight line (L_1) is separated by a distance (d) from the straight line (L_2) passing the axis (A) in parallel thereto. For this reason, the bending angle of the supporting frame (1) is greatly affected by the distance d between the axis (A) and the line (L_1). The greater the distance d, the smaller is the bending angle in the direction of an arrow -X, as indicated in Fig. 3b. However, this makes it easy to bent the supporting frame (1) in the opposite direction, i.e., in the direction of an arrow X in Fig. 3b. Thus, the bending angle of the supporting frame (1) may be determined according to a sort of artificial organs to be produced or objects to be implanted.

In the above embodiment, the prosthetic material is composed of a textile of the plain weave structure, but weaves of the textile are not limited thereto. There may be used textiles or fabrics constituted by any other weaves including twill weave, satoen weave and respective variations. Also, there may be used tubular

or flat knitted goods such as, for example, warp knitted fabrics, weft knitted fabrics, plain stitch fabrics, interlock fabrics, fleecy fabrics, and tuck stitch fabrics.

Fig. 5 shows a modification of a tubular supporting frame for use in the artificial trachea of the present invention. This supporting frame is made of a biocompatible synthetic resin in the form of inverted Y-shape, and is composed of a trachea portion (4), a bifurcated portion (5), and bronchus portions (6, 6'). The trachea portion (4) comprises a plurality of ring portions (2) arranged on a common axis, and plural pairs of connecting portions (3) extending between neighboring two ring portions (2) to connect them each other. Similarly, each bronchus portion (6, 6') is composed of a plurality of ring portions (8) arranged on a common axis, and plural pairs of connecting portions (9) extending between neighboring two ring portions (8) to connect them each other.

The lowermost ring portion (2) is connected to the uppermost ring portions (8) of the bronchus portions (6) by a pair of a connecting portion extending therefrom to form a bifurcated portion (5), and the uppermost ring portions (8a, 8a') are connected each other at their edges. The left bronchus portion 6' (in fig. 5, right portion) extends sideways at an angle smaller than that of the right bronchus portion (6), but has a length longer than that of the right bronchus portion (6).

The above tubular supporting frame is covered with a medical prosthetic material to form an artificial trachea. The medical prosthetic material is composed of a woven fabric, a knitted fabric or a nonwoven fabric.

Fig. 6 shows an artificial blood vessel according to the present invention. This artificial blood vessel is composed of a tubular supporting frame 1 and a union cloth 15 spirally wound thereon to form a tubular wall of the artificial blood vessel. The union cloth 15 comprises absorbable macromolecular yarns and non-absorbable macromolecular yarns. The above union cloth may be replaced with a non-woven fabric.

The artificial blood vessel may be provided on its outer surface with a coating of a protein such as collagen or gelatin, and on its inner surface with a coating of an anti-thrombogenic material.

When such an artificial blood vessel is implanted in the body, one of the constituents of the tubular wall, i.e., absorbable macromolecular yarns are decomposed and absorbed in the body, thereby forming pores between non-absorbable macromolecular yarns. The granulation tissues enter into the pores so that the artificial blood vessel adheres to the surrounding tissues and is fixed thereto. Since the medical prosthetic material is composed of union cloth with a high density, the artificial blood vessel is airtight and watertight. Thus, the artificial blood vessel is initially stiffened, but it is softened gradually as the absorbable macromolecular yarns are dissolved and absorbed in the body. It is possible to minimize an obstacle due to implantation as well as to avoid occurrence of inflammation.

The construction of Fig. 1 may be applied to an artificial trachea, which comprises a tubular supporting frame as shown in Fig. 1, and a medical prosthetic material arranged on its inner and/or outer surfaces. In such a case, the supporting frame is generally formed with fluoroplastics so as to have an inner diameter of 20 to 30 mm, a length of 10 to 50 mm, and a thickness of 1 mm. The medical prosthetic material may be a woven fabric composed of absorbable macromolecular yarns and non-absorbable macromolecular yarns, as shown in Fig. 4. The outer surface of this artificial trachea may be coated with a protein such as collagen or gelatin.

Since the outer wall of such an artificial trachea is composed of a union cloth with a high density, it is kept airtight and water tight just after implantation of the artificial trachea so that the expired air and inspired air will not escape. Thus, the artificial trachea will fulfil the intended function effectively. Also, there is almost no occurrence of microbism as external bacteria are prevented from passing through the cloth. The absorbable macromolecular yarns constituting the union cloth is decomposed and absorbed in the body with the lapse of time to form openings in the tubular wall of the artificial trachea. For this reason, the granulation tissues enter into the openings formed between the remaining non-absorbable macromolecular yarns and encapsulate the artificial trachea to form a composite structure.

Fig. 7 shows a weave pattern of a medical prosthetic material constructed by passing weft yarns 16 alternately under and over warp yarns 17 across the width of the fabric. The weft yarns 16 are twist yarns composed of a non-absorbable macromolecular yarn 16a and an absorbable macromolecular yarn 16b, while the warp yarns 17 are doubled yarns composed of a non-absorbable macromolecular yarn 17a and an absorbable macromolecular yarn 17b.

The above absorbable and non-absorbable macromolecular yarns may be monofilament yarns or multifilament yarns. It is however preferred to use false twist yarns to improve airtightness and flexibility of the cloth. Since the woven fabric is constructed by weaving two kinds of composite yarns, i.e., doubled yarns and twist yarns, the size of the openings to be formed in the plain weave fabric after implantation may be controlled by variation of fiber diameters of the absorbable and non-absorbable macromolecular yarns, by changing the distance between neighboring two warp yarns or weft yarns, or by changing the number of

yarns constituting doubled yarns or twist yarns.

In the above embodiment, the medical prosthetic material is composed of a woven fabric including double yarns as the warp yarns, and twist yarns as the weft yarns, but it may be a woven fabric or a knitted fabric, of which both the warp yarns and weft yarns are composed of either double yarns or twist yarns. Also, it is possible to use, as the medical prosthetic material, woven fabrics or knitted fabrics in which either the warp yarns or weft yarns are composed of double yarns or twist yarns, while the other being composed of non-absorbable macromolecular yarns.

In the above case, it is preferred to use twist yarns which have a twist angle given by θ in Fig 9, ranging from 45 to 88°, in particular, 65 to 85°.

It is preferrad to use non-absorbable macromolecular yarns composed of single yarns having a diameter ranging from 0.1 to 100 µm, in particular, 1.0 to 40 µm. If the single yarns with a diameter exceeding 100 µm are employed, the woven fabric becomes rigid and causes inflammation after implantation of the artificial tubular organ. If the single yarns with a diameter of less than 0.1 µm are used, it is difficult to produce.

Fig. 8 is an enlarged fragmentary plan view of a nonwoven fabric used as a medical prosthetic material. This nonwoven fabric is composed of absorbable fibers 17 and non-absorbable fibers 18, which are intersected each other and interlocked at crossed points. The nonwoven fabric may be produced by a process comprising the steps of separately spinning an absorbable macromolecular material and an non-absorbable macromolecular material into filaments through nozzles, cutting the filaments into fibers, spraying the fibers onto a surface of a conveyer or a rotating surface of a columnar or cylindrical mandrel, and interlocking the resultant layered fibers at their crossed points by a physical process, for example, needling and water jet. The layered fibers may be interlocked at their crossed points by any other processes, for example, by heating, or by chemical treatment such as alkali treatment and solvent treatment. By spraying the fibers on the surface of the mandrel, it is possible to obtain a tubular nonwoven fabric by removing the mandrel from the product.

The fibers used for nonwoven fabric may be long fibers, or short fibers, or a combination of long fibers and short fibers. The nonwoven fabric is generally produced in the form of a flat or tubular shape.

It is preferred to use nonwoven fabrics with a bulk density of 0.005 to 0.60 g/cm^3 as a medical prosthetic material. If the bulk density of the nonwoven fabric exceeds 0.60 g/cm^3, the nonwoven fabric becomes rigid and causes inflammation resulting from implantation of the artificial tubular organ. If the bulk density is loss than 0.005 g/cm^3 are used, the mechanical properties of the nonwoven fabric becomes lowered.

Also, it is preferred that the nonwoven fabric is at least 0.1 mm thick, in particular, 1 to 10 mm thick. If the thickness of the nonwoven fabric is less than 0.1 mm, durability becomes lowered.

It is preferred that the nonwoven fabric has an extension percentage of at least 5 %, in particular, from 10 to 25 %. The nonwoven fabric with such an extension percentage is particularly suitable for artificial tubular organs which is given the internal pressure, such as artificial blood vessels and artificial trachea.

EXPERIMENT 1

There were prepared artificial tracheas comprising a tubular supporting frame (23 mm outside diameter, 21 mm inside diameter, 60 mm length) of polytetrafluoroethylene having a structure as shown in Fig. 2, and a tubular mesh of polyester arranged in the lumen of the supporting frame and fixed thereto with stitches. The supporting frame is composed of ten ring portions and nine pairs of connecting portions (4 mm width by 4 mm length by 1 mm thick). The outermost ring portions are 4 mm in length, while other ring portions are 2 mm in length.

Using male dogs with the weight of 10 to 15 Kg, animal experiments were conducted by implanting each artificial trachea in the dog. Results are summarized in Table 1.

In the table, early death means that the dog died within 4 weeks, while long-term survival means that the dog survived more than 4 weeks. The cause of death are classified into the following groups:

A: death caused by the supporting frame (e.g., deformation, migration);

B: death caused by the mesh (e.g., air leakage, supernumerary granulation);

C: death caused by surgical operation or trachea (e.g., stenosis or disherence at the anastomosed portion);

D: death caused by disease (e.g., obstruction of the airway caused by sputum);

E: death caused by inflammation; and

F: death caused by nacrosis.

COMPARATIVE EXPERIMENT 1

There were prepared artificial tracheae each comprising a supporting frame of polyethylene formed into a semi cylindrical form shown in Fig. 9 and covered with a mesh of polyester. Using male dog with the weight of 10 to 14 Kg, animal experiments were conducted in the same manner as that in Experiment 1. Results are shown in Table 1.

COMPARATIVE EXPERIMENT 2

There were prepared artificial tracheae each comprising a supporting frame of polyethylene formed into an arched shape shown in Fig. 10 and covered with a mesh of polyester. Using dogs with the weight of 7 to 13 Kg, animal experiments were conducted in the same manner as that in Experiment 1. Results are shown in Table 1.

COMPARATIVE EXPERIMENT 3

Using commercially available polyethylene tube (produced by Dow Chemicals) having a structure as shown in Fig. 11, animal experiments were conducted in the same manner as that in Experiment 1. The dogs used have the weight of 9 to 13 Kg.

Table 1

	Total	Early death		long-time survival		
	Head	Head	cause	Death	cause	survival
Ex. 1	28	13	B: 10 C: 2 D: 1	4	B: 1 C: 1 Victim: 1 Unknown: 1	11
Comp. Ex. 1	20	8	A: 1 B: 5 C: 2	12	A: 4 B: 1 C: 6 Other: 1	0
Comp. Ex. 2	5	0	-	5	A: 5	0
Comp. Ex. 3	10	2	B: 1 F: 5	8	A: 6 C: 2	0

From the results shown in Table 1, it will be seen that there is no case in which death is caused by use of the supporting frame of the present invention. In contrast therewith, the artificial tracheae of comparative examples 1 and 2 cause death due to deformation of the supporting frame. On the other hand, the artificial tracheae of comparative Example 3 resulted in migration of the trachea, while the remaining head survived more than 4 weeks.

EXPERIMENTS 2-5

Using polyethylene terephthalate (herein after referred to as PET) yarns of 150 denier/30 filament and polyglycolic acic (herein after referred to as PGA) yarn of 120 denier/6 filament as weft yarns and warp yarns, there were prepared plain woven fabrics of 2/2 having a construction of Fig. 4. A distance (L) between neighboring PET yarns are varied as shown in Table 2. Each plain woven fabric was implanted in a subdorsal site of a dog, and the condition of implantation of the fabric was visually observed after 6 waeks have elapsed. Results are shown in Table 2.

In Table 2, "good" means that the fabric is fixed to the surrounding tissue by invasion of the granulation tissues into pores of the fabric, "better" means that the fabric is exfoliated from the surrounding tissue although the granulation tissues have invaded into pores of the fabric, and "bad" means that no invasion of granulation tissues into the pores of the fabric has been observed.

COMPARATIVE EXPERIMENTS 4-6

Using the same PET yarns as that of Experiments 2, there were prepared plain woven fabrics of 2/2 having a construction of Fig. 4, with a distance (L) between neighboring PET yarns being varied as shown in Table 2. Each plain woven fabric was implanted in a subdorsal site of a dog, and the condition of implantation of the fabric was visually observed after 6 weeks have elapsed. Results are shown in Table 2.

Table 2

	Distance (L_1)	Judgement
Ex. 2	307 μm	good
Ex. 3	241 μm	good
Ex. 4	153 μm	good
Ex. 5	126 μm	better
Comp. Ex. 4	101 μm	bad
Comp. Ex. 5	95 μm	bad
Comp. Ex. 6	74 μm	bad

As will be understood from the results shown in Table 2, if the distance (L) between the neighboring PET yarns is less than 101 μm like as the fabrics of the comparative experments, no invasion of the granulation tissues into the fabric occurs and the fabric is never fixed to the surrounding tissues.

EXPERIMENTS 6-9

Using a PET yarn of 70 denier/36 filament and a PGA yarn of 12 denier/6 filament or a PGA yarn of 6 denier/3 filament, there was prepared a doubled yarn to be used as a weft yarn for the plain woven fabric of Fig. 7 by yarn doubling. Also, there was prepared an S twist yarn to be used as a warp yarn for the plain woven fabric of Fig. 7 by twisting the above doubled yarn in the direction of S by 200 T/M. Using the resultant doubled yarn and S twist yarn, there were prepared plain woven fabrics of 1/1 having a construction of Fig. 7. A distance (L) between neighboring PET yarns are varied as shown in Table 3.

Each plain woven fabric was coated with a 10 wt% aqueous solution of collagen, dried and then implanted in a subdorsal site of a dog. After 6 weeks have elapsed, the condition of implantation of the fabric was visually observed. Results are shown in Table 3.

In Table 3, "good" means that the fabric is fixed to the surrounding tissue by invasion of the granulation tissues into pores of the fabric, "better" means that the fabric is exfoliated from the surrounding tissue

although the granulation tissues have invaded into pores of the fabric, and "bad" means that no invasion of granulation tissues into the pores of the fabric has been observed.

COMPARATIVE EXPERIMENTS 7-8

Using PET yarns of 100 denier/36 filament, there were prepared plain woven fabrics of 1/1 having a construction of Fig. 7. A distance (L) between neighboring PET yarns was varied as shown in Table 3. Each plain woven fabric was implanted in a subdorsal site of a dog, and the condition of implantation of the fabric was visually observed after 8 weeks have elapsed. Results are also shown in Table 3.

Table 3

	PGA yarn	Distance (L)	Judgement
Ex. 6	12d/6f	340 μm	good
Ex. 7	12d/6f	281 μm	good
Ex. 8	12d/3f	209 μm	good
Ex. 9	6d/3f	147 μm	good
Comp. Ex. 7	6d/3f	105 μm	bad
Comp. Ex. 8	-	95 μm	bad

As will be understood from the results shown in Table 3, if the distance (L) between the neighboring PET yarns is less than 110 μm like as the fabrics of the comparative experiments, no invasion of the granulation tissues into the fabric occurs and the fabric is never fixed to the surrounding tissues.

EXPERIMENTS 10-13

Using PET and PGA as raw materials, there were prepared nonwoven fabrics by separately spinning PET and PGA with water jet into filaments through respective nozzles, and then cutting the filaments into fibers to form PET fibers with a diameter of 41.3 μm and PGA fibers with a diameter of 38.4μm, spraying the resultant fibers onto a conveyer surface, and interlocking the resultant layered fibers at their crossed points by needling. The non-woven fabric has a thickness of 1.6 mm, and a bulk density of 0.12 g/cm^3. A mixing ratio of PET fibers to PGE fibers was determined such that the pores formed in the nonwoven fabric after decomposition of PAG fibers has an average diameter as shown in Table 4.

Each nonwoven fabric was coated with a 10 wt% aqueous solution of collagen, dried, and then implanted in a subdorsal site of a dog. After 6 weeks have elapsed, the condition of implantation of the fabric was visually observed. Results are shown in Table 4.

In Table 4, "good" means that the fabric is fixed to the surrounding tissue by invasion of the granulation tissues into pores of the fabric. "better" means that the fabric is exfoliated from the surrounding tissue although the granulation tissues have invaded into pores of the fabric, and "bad" means that no invasion of granulation tissues into the pores of the fabric has been observed.

Table 4

	Amount of PGA fabric	Diameter of pores	Judgement
Ex. 10	74	310 μm	good
Ex. 11	59	225 μm	good
Ex. 12	43	162 μm	good
Ex. 13	32	134 μm	good
Comp. Ex. 9	15	108 μm	bad

As will be understood from the results shown in Table 4, if the distance (L) between the neighboring PET yarns is less than 110 μm like as the fabrics of the comparative experiments, no invasion of the granulation tissues into the fabric occurs and the fabric is never fixed to the surrounding tissues.

EXPERIMENT 14

Using doubled yarns composed of a polypropylene (hereinafter referred to as PP) yarn of 75 denier/24 filament and a PGA yarn of 18 denier/6 filament as weft yarns and warp yarns, there were prepared tubular plain woven fabrics of 1/1 having a construction of Fig. 7 such that they have an inner diameter of 9 mm and a length of 6 cm. A distance (L) between neighboring PP yarns was 433 μm.

EXPERIMENT 15

Using doubled yarns composed of a high density polyethylene (density: 0.96 g/cm^3, hereinafter referred to as PE) yarn of 70 denier/12 filament and a PGA yarn of 18 denier/6 filament as weft yarns and warp yarns, tubular plain woven fabrics of Fig.7 were prepared in the same manner as that in Experiment 14. The distance (L) between neighboring PE yarns was 513 μm.

EXPERIMENT 16

Using doubled yarns composed of a PET yarn of 75 denier/24 filament and a PGA yarn of 18 denier/6 filament as weft yarns and warp yarns, tubular plain woven fabrics of Fig. 7 were prepared in the same manner as that in Experiment 14. The distance (L) between neighboring PET yarns was 396 μm.

EXPERIMENT 17

Using doubled yarns composed of a 66-nylon (hereinafter referred to as NY) yarn of 70 denier/36 filament and a PGA yarn of 18 denier/6 filament as weft yarns and warp yarns, tubular plain woven fabrics of Fig. 7 were prepared in the same manner as that in Experiment 14. The distance (L) between neighboring NY yarns was 421 μm.

The plain woven fabrics prepared in Experiments 14-17 were coated with a 10 wt% aqueous solution of collagen and then dried to form a thin layer of collagen on the outer surface of the tubular fabrics. Each tubular woven fabric was implanted in a thoracotrophic aorta descendens of a dog. After 3 months have elapsed, the condition of implantation of the tubular fabric was visually observed. Results are shown in Table 5.

In Table 5, "good" means the fact that a neo-membrane was observed on the inner wall of the tubular fabric, but the granulation tissue was never observed in the lumen of the tubular fabric, "better" means that short granulation tissues were observed on the periphery of the inner wall of the tubular woven fabric, and "bad" means the fact that the granulation tissues grow across the lumen of the tubular woven fabric.

Table 5

	Material of non-absorbable yarn	Judgement
Ex. 14	PP	good
Ex. 15	PE	good
Ex. 16	PET	better
Ex. 17	NY	better

As will be understood from the above results, by using the tubular woven fabric composed of absorbable yarns and nonabsorbable yarns as a medical prosthetic material, it is possible to permit the formation of neo-membrane on the inner wall of the tubular fabric without causing the growth of the granulation tissue in the lumen of the tubular fabric.

Claims

1. An artificial tubular organ composed of a tubular supporting frame made of a plastic material and provided on its at least one surface with a medical prosthetic material, said supporting frame being composed of a plurality of ring portions arranged on an axis, and a plural pairs of connecting portions extending between neighboring two ring portions to connect them each other, every other pairs of said connecting portions being diametrically arranged on said ring portions, the remaining pairs of said connecting portions being arranged such that the plane containing their center lines intersects at right angles with the plane containing the center lines of a pair of diametrically arranged connecting portions, said medical prosthetic material being composed of at least one fabric selected from the group consisting of woven fabrics, nonwoven fabrics, and knitted fabrics.

2. An artificial tubular organ according to claim 1 wherein each pair of the connecting portions of the tubular supporting frame are diametrically arranged between the ring portions.

3. An artificial tubular organ according to claim 1 or 2 wherein said medical prosthetic material is composed of a fabric selected from the group consisting of woven fabrics, nonwoven fabrics, and knitted fabrics, and wherein the fabric is composed of absorbable macromolecular yarns and nonabsorbable macromolecular yarns.

4. An artificial tubular organ according to claim 1, 2 or 3 wherein yarns are double yarns or twist yarns composed of at least one absorbable macromolecular yarns and at least one nonabsorbable macromolecular yarns.

5. An artificial tubular organ according to any one of claims 1 to 4 wherein the fabric is a union cloth composed of absorbable macromolecular yarns and nonabsorbable macromolecular yarns.

6. An artificial tubular organ according to claim 3, 4 or 5 wherein nonabsorbable macromolecular yarns is composed of fibers made of a material selected from the group consisting of polyesters, polyolefins, polyamide resins, fluoroplastics, chlorine resins, polyurethane resins, cellulose derivatives, and natural fibers.

7. An artificial tubular organ according to any one of claims 3 to 6 wherein nonabsorbable macromolecular yarns is composed of one of polyolefine fibers.

8. An artificial tubular organ according to any one of claims 3 to 7 wherein said fabrics or yarns are

coated with a protein.

9. An artificial tubular organ according to any one of claims 3 to 8 wherein said absorbable macromolecular yearns are included in the fabric so that they are dissolved and absorbed in the organism after implantation to form openings or pores having an average diameter of 110 µm and being present at least 20 % in the fabric.

Fig. 1

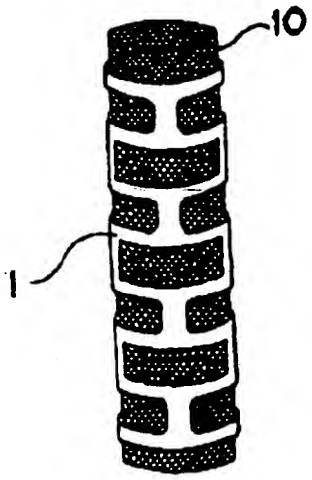


Fig. 2

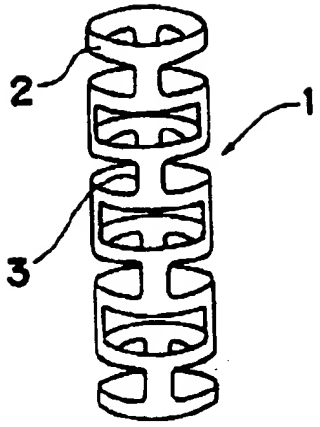


Fig. 3(a)

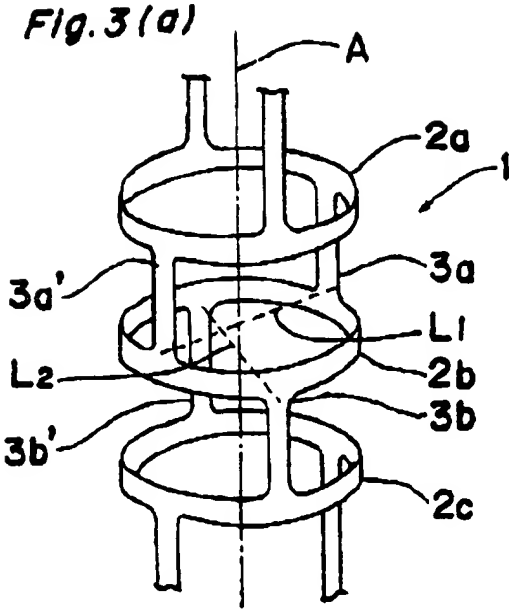


Fig. 3(b)

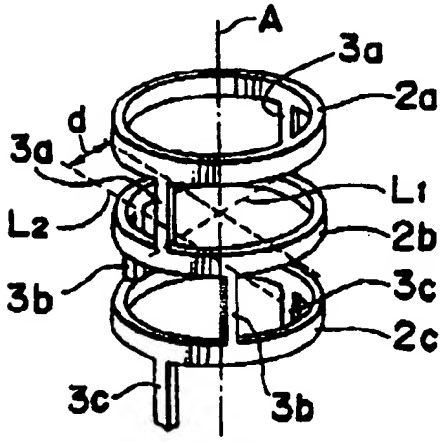


Fig. 4

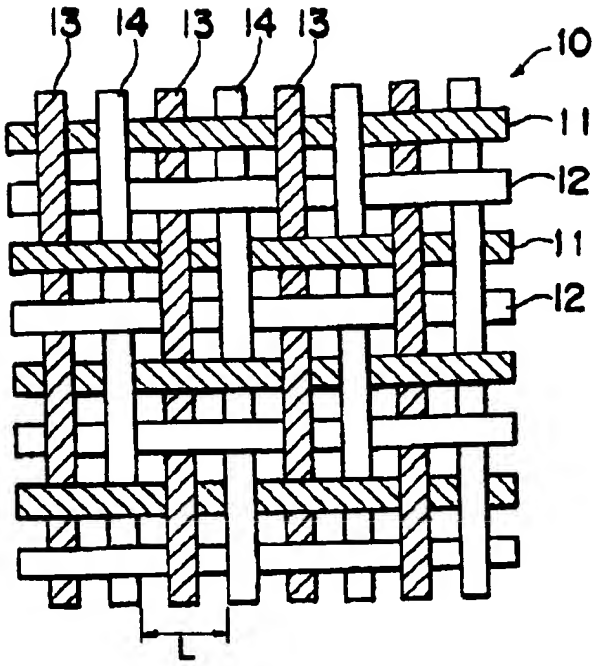


Fig. 5

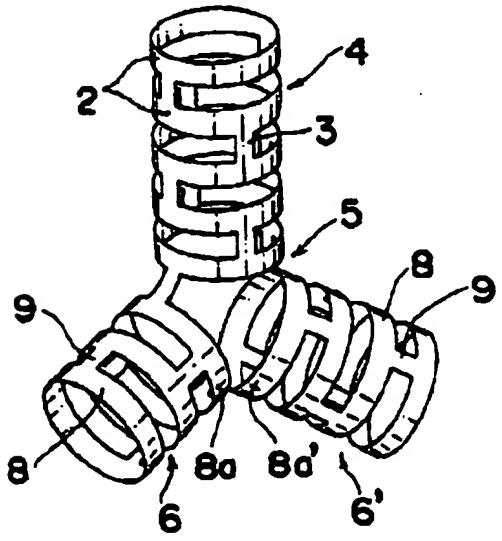


Fig. 6

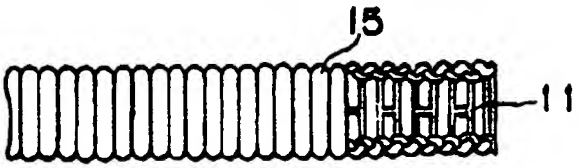


Fig. 7

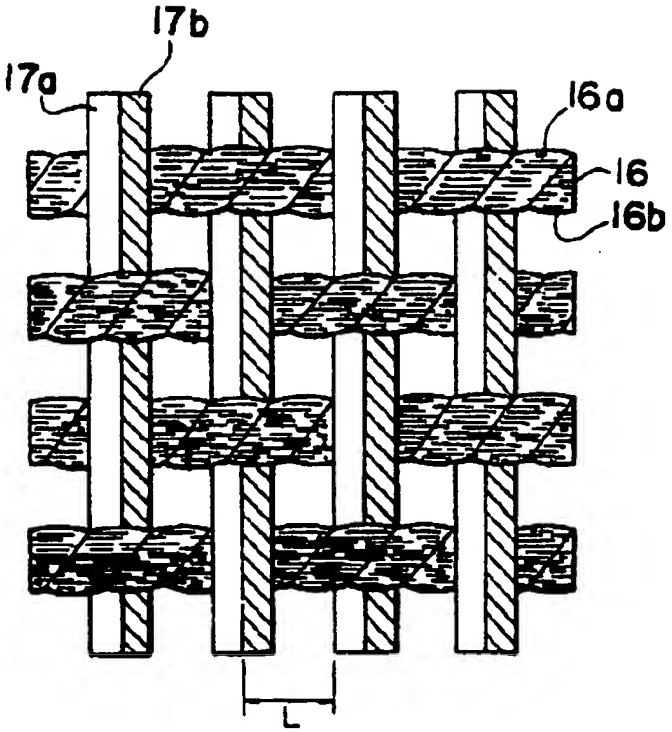


Fig. 8

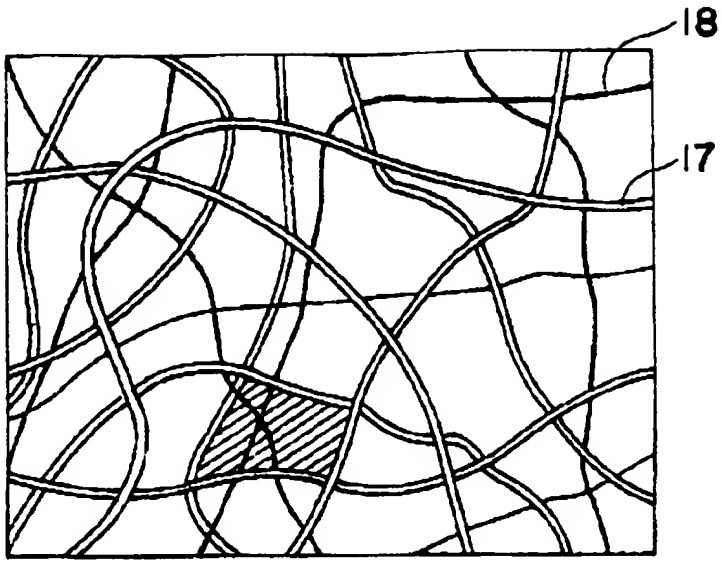


Fig. 9

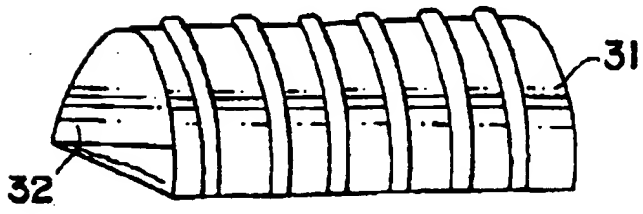


Fig. 10

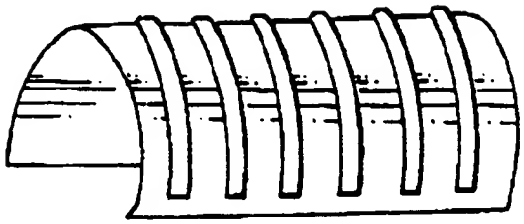
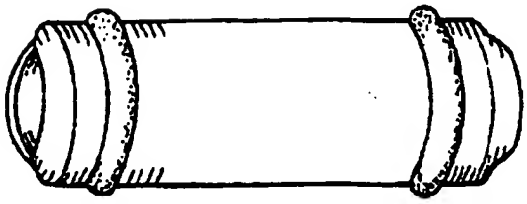


Fig. 11



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 11 0896

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	FR-A-2 333 487 (RHONE-POULENC) " Page 2, line 33 - page 3, line 10; page 3, lines 23-26; page 4, lines 1-8; claims 1,2,10,16,18; figure 3 "	1,2	A 61 F 2/04 A 61 F 2/06 A 61 L 27/00 D 03 D 15/00
A		3,6,9	
Y	EP-A-0 364 787 (EXPANDABLE GRAFTS) " Figure 7; column 13, line 53 - column 14, line 9; claim 6 "	1,2	
A	US-A-4 878 908 (LINDEMANN) " Column 4, lines 50-53; column 4, line 60 - column 5, line 3; figures 3,5,6 "	1,2	
A	DE-B-1 185 332 (ETHICON) " Column 5, lines 17-21; column 10, lines 5-19; figure 4 "	1,8	
A	EP-A-0 334 024 (A.C.C.) " Claims "	3,5,8,9	
A	DE-A-1 541 253 (ETHICON) " Page 4, line 6 - page 5, line 5; claims "	3,6-9	
A	EP-A-0 334 045 (A.C.C.)		
A	EP-A-0 108 171 (MEADOX)		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)
A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	24 September 91	KLEIN C.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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(54) Method and apparatus for bilateral intra-aortic bypass.

(57) A bilateral intra-aortic bypass graft (150) and method and apparatus for repairing an abdominal aortic aneurysm (151) includes two tubular grafts (160A,160B) which are intraluminally delivered to the aorta (152) and secured to the aorta (152) by the expansion and deformation of two expandable and deformable tubular members (166A,166B).

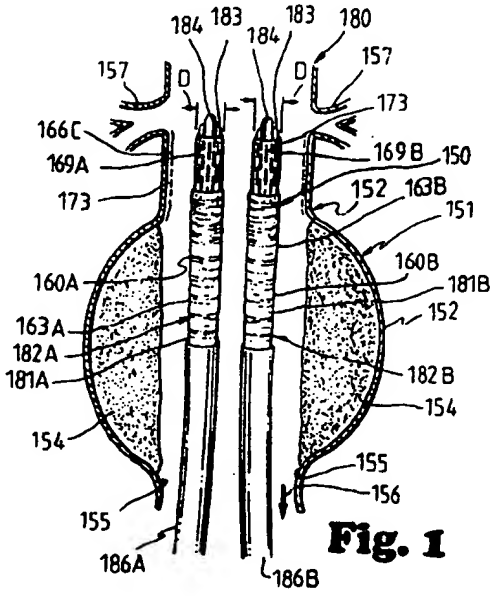

Fig. 1

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BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The invention relates to a bilateral intra-aortic bypass graft for intraluminal delivery, and a method and apparatus for repairing an abdominal aortic aneurysm.

2. DESCRIPTION OF THE PRIOR ART

An abdominal aortic aneurysm is a sac caused by an abnormal dilation of the wall of the aorta, a major artery of the body, as it passes through the abdomen. The abdomen is that portion of the body which lies between the thorax and the pelvis. It contains a cavity, known as the abdominal cavity, separated by the diaphragm from the thoracic cavity and lined with a serous membrane, the peritoneum. The aorta is the main trunk, or artery, from which the systemic arterial system proceeds. It arises from the left ventricle of the heart, passes upward, bends over and passes down through the thorax and through the abdomen to about the level of the fourth lumbar vertebra, where it divides into the two common iliac arteries.

The aneurysm usually arises in the infrarenal portion of the arteriosclerotically diseased aorta, for example, below the kidneys. When left untreated, the aneurysm will eventually cause rupture of the sac with ensuing fatal hemorrhaging in a very short time. High mortality associated with the rupture has led to the present state of the art and the transabdominal surgical repair of abdominal aortic aneurysms. Surgery involving the abdominal wall, however, is a major undertaking with associated high risks. There is considerable mortality and morbidity associated with this magnitude of surgical intervention, which in essence involves replacing the diseased and aneurysmal segment of blood vessel with a prosthetic device which typically is a synthetic tube, or graft, usually fabricated of either DACRON®, TEFLON®, or other suitable material.

To perform the surgical procedure, requires exposure of the aorta through an abdominal incision, which can extend from the rib cage to the pubis. The aorta must be closed both above and below the aneurysm, so that the aneurysm can then be opened and the thrombus, or blood clot, and arteriosclerotic debris removed. Small arterial branches from the back wall of the aorta are tied off. The DACRON® tube, or graft, of approximately the same size of the normal aorta, is sutured in place, thereby replacing the aneurysm. Blood flow is then reestablished through the graft. It is necessary to move the intestines in order to get to the back wall of the abdomen prior to clamping off the aorta.

If the surgery is performed prior to rupturing of the abdominal aorta aneurysm, the survival rate of treated patients is markedly higher than if the surgery is performed after the aneurysm ruptures, although the mortality rate is still quite high. If the surgery is performed prior to the aneurysm rupturing, the mortality rate is typically less than 5%. Conventional surgery performed after the rupture of the aneurysm is significantly higher, one study reporting a mortality rate of 66.7%. Although abdominal aortic aneurysms can be detected from routine examinations, the patient does not experience any pain from the condition. Thus, if the patient is not receiving routine examinations, it is possible that the aneurysm will progress to the rupture stage, wherein the mortality rates are significantly higher.

Disadvantages associated with the conventional, prior art surgery, in addition to the high mortality rate, are: the extended recovery period associated with such surgery; difficulties in suturing the graft, or tube, to the aorta; the loss of the existing thrombosis to support and reinforce the graft; the unsuitability of the surgery for many patients having abdominal aortic aneurysms; and the problems associated with the performing the surgery on an emergency basis after the aneurysm has ruptured. As to the extent of recovery, a patient can expect to spend form 1 to 2 weeks in the hospital after the surgery, a major portion of which is spent in the intensive care unit, and a convalescence period at home from 2 to 3 months, particularly if the patient has other illness such as heart, lung, liver, and/or kidney disease, in which case the hospital stay is also lengthened. Since the graft must be secured, or sutured, to the remaining portion of the aorta, it is many times difficult to perform the suturing step because of thrombosis present on the remaining portion of the aorta, and that remaining portion of the aorta wall may many times be friable, or easily crumbled.

Since the thrombosis is totally removed in the prior art surgery, the new graft does not have the benefit of the previously existing thrombosis therein, which could be utilized to support and reinforce the graft, were the graft to be able to be inserted within the existing thrombosis. Since many patients having abdominal aortic aneurysms have other chronic illnesses, such as heart, lung, liver, and/or kidney disease, coupled with the fact that many of these patients are older, the average age being approximately 67 years old, these patients are not ideal candidates for such surgery, which is considered major surgery. Such patients have difficulties in surviving the operation. Lastly, once the aneurysm has ruptured, it is difficult to perform a conventional surgery on an expedited basis because of the extent of the surgery.

It has been previously proposed to repair abdominal aortic aneurysms by intraluminal delivery of an aortic graft disposed upon a catheter, and securing the graft within the aorta by expansion and deformation of an expandable deformable member associat-

ed with the graft by expanding and inflating a portion of the catheter which contacts the tubular member. Because of the relatively large diameter of the catheter and associated graft necessary for implantation within the aorta, some difficulties have been sometimes encountered, such as spasms associated with the access body vessel such as the femoral artery. Additional problems sometimes encountered with this method or repairing an abdominal aortic aneurysm have been kinking and/or twisting of the flexible, collapsible graft during and/or after implantation of the graft.

Accordingly, prior to the development of the present invention, there has been no bilateral intra-aortic bypass graft for intraluminal delivery, or method and apparatus for repairing an abdominal aortic aneurysm, which: does not have a relatively high morbidity and mortality rate; does not have an extended recovery period; does not require suturing the graft to the remaining aorta wall; permits the existing thrombosis therein to support and reinforce the graft; is suitable for older patients with chronic illnesses; is less susceptible to kinking and/or twisting of the graft; and is able to use a smaller diameter delivery system. Therefore, the art has sought a bilateral intra-aortic bypass graft for intraluminal delivery, and method and apparatus for repairing an abdominal aortic aneurysm which is believed to: not have a high morbidity and mortality rate; does not require an abdominal incision and general anesthesia; not require an extended recovery period; not require suturing the graft to the remaining aortic wall; permit the existing aortic wall and thrombosis therein to be retained to reinforce and support the aortic graft; be suitable for patients having other chronic illnesses; be less susceptible to kinking and/or twisting of the graft and permit the use of a smaller diameter delivery system.

SUMMARY OF THE INVENTION

In accordance with the invention, the foregoing advantages have been achieved through the method and apparatus for bilateral intra-aortic graft of the present invention. The method for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith may include the steps of: connecting a first tube to a first expandable and deformable, tubular member; connecting a second tube to a second expandable and deformable, tubular member; disposing the first tube and first tubular member upon a first catheter, disposing the second tube and second tubular member upon a second catheter, each catheter having an expandable, inflatable portion with the tubular members disposed upon the expandable, inflatable portions; intraluminally delivering the first and second tubes, tubular members, and catheters to the aorta and disposing at least a portion of each tube within the abdominal aortic aneurysm; and expanding the expandable, inflatable portion of each catheter to expand and deform the tubular members to force the tubular members radially outwardly into contact with the aorta and each other, to secure the tubular members and a least a portion of each tube within the aorta, whereby the tubes provide a bilateral fluid passageway through the abdominal aortic aneurysm.

Another feature of the present invention may include the step of simultaneously expanding the expandable, inflatable portions of each catheter. An additional feature of the present invention is that the first and second tubes may each have first and second ends, the first end of each tube being connected to a tubular member and being disposed within the aorta; and the second end of the first tube may be disposed within one of the iliac arteries, and the second end of the second end may be disposed within the other iliac artery.

A further feature of the present invention is that a third expandable and deformable, tubular member may be connected to the second end of the first tube; a fourth expandable and deformable, tubular member may be connected to the second end of the second tube; and the third and fourth tubular members are expanded and deformed to force the third and fourth tubular members radially outwardly into contact with an iliac artery by the expansion of the expandable, inflatable portion of each catheter associated with each tube. Another feature of the present invention may include the steps of forming each tube of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, by aligning the plurality of tubular members with their longitudinal axes being substantially parallel with other, each tubular member being detached, and spaced apart, from adjacent tubular members; and embedding the plurality of tubular members within a layer of deformable and expandable plastic material. The plastic material may be silicone, polytetrafluoroethylene, expanded polytetrafluoroethylene, or expanded polyurethane.

An additional feature of the present invention may include the step of simultaneously expanding the expandable, inflatable portion of each catheter to simultaneously expand and deform the first and second tubular members and the plurality of tubular members of each tube which are embedded in the deformable and expandable plastic material. A further feature of the present invention may include the step of connecting the first and second tubular members to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is to be connected.

A further feature of the present invention may include the steps of: disposing a fifth expandable and deformable tubular member upon a third catheter

having an expandable, inflatable portion, with the fifth tubular member being disposed upon the expandable, inflatable portion; intraluminally delivering the fifth tubular member and third catheter to the aorta; expanding the expandable, inflatable portion of the third catheter to expand and deform the fifth tubular member to force the third tubular member radially outwardly into a connect with the aorta to secure the fifth tubular member within the aorta; the foregoing steps being conducted prior to the intraluminal delivery of the first and second tubes, tubular members, and catheters, whereupon the simultaneous expansion of the expandable, inflatable portions of the first and second catheters, the first and second tubular members are expanded and deformed radially outwardly into connect with the fifth tubular member and each other, to secure the first and second tubular members within the aorta and within the fifth tubular member.

An additional feature of the present invention may include the steps of forming each tube of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, by aligning the plurality of tubular members with their longitudinal axes being substantially parallel with other, each tubular member being spaced apart from adjacent tubular members with a single, flexible connector member being disposed between adjacent tubular members; and embedding the plurality of tubular members within a layer of deformable and expandable plastic material.

In accordance with the invention, the foregoing advantages have also been achieved through the present bilateral intra-aortic bypass graft for intraluminal delivery to repair an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith. This aspect of the present invention includes: a first tube having first and second ends and a wall surface disposed between the two ends, at least a portion of the first tube adapted to be disposed within the abdominal aortic aneurysm; a second tube having first and second ends and a wall surface disposed between the two ends, at least a portion of the second tube adapted to be disposed within the abdominal aortic aneurysm; and means for securing the first ends of the first and second tubes to the aorta, the securing means including first and second tubular members, each tubular member having first and second ends, the first tube being connected to the first tubular member and the second tube being connected to the second tubular member, the tubular members having a first diameter which permits intraluminal delivery of the tubular members and tubes into the aorta and the tubular members having a second, expanded and deformed diameter, with at least a portion of the first and second tubular members in an abutting relationship, upon the application from the interior of the tubular members of a radially, outwardly extending force, the second diameter being variable and dependent upon the amount of force applied to the tubular member, whereby the tubular members may be expanded and deformed to secure the first ends of the tubular members to the aorta and a bilateral fluid passageway is formed within the abdominal aorta aneurysm.

Another feature of the present invention is that at least a portion of the first and second tubes are in an abutting relationship with each other when the first and second tubular members have their second, expanded and deformed diameter. An additional feature of the present invention is that a third expandable and deformable tubular member may be connected to the second end of the first tube; a fourth expandable and deformable tubular member may be connected to the second end of the second tube; and the third and fourth tubular members may be expanded and deformed to force the third and fourth tubular members radially outwardly into contact with an iliac artery by the expansion of the expandable, inflatable portion of each catheter associated with each tube.

A further feature of the present invention is that each tube may be formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members may be embedded with a layer of a deformable and expandable plastic material. The plastic material may be silicone, polytetrafluoroethylene, expanded polytetrafluoroethylene, or expanded polyurethane.

Another feature of the present invention is that the first and second tubular members may be connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic of the tube to which it is to be connected.

An additional feature of the present invention is that each tube may be formed of a plurality of expandable, and deformable tubular members, each tubular member having a longitudinal axis with a plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other; each tubular member being spaced apart from adjacent tubular members with a single, flexible connector member being disposed between adjacent tubular members; and the plurality of tubular members may be embedded within a layer of a deformable and expandable material. A further feature of the present invention is that the first and second tubular members may be connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is

to be connected.

In accordance with the present invention, the foregoing advantages have also been achieved through the present apparatus for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith. The present invention includes: first and second tubes, each tube having first and second ends and a wall surface disposed between the two ends; first and second expandable and deformable tubular members, each expandable and deformable tubular members having first and second ends and a smooth outer wall surface disposed between the first and second ends, the first end of a tube being secured to a second end of a tubular member, the expansion and deformation of the tubular members being controllable; and two catheters, each catheter having an expandable, inflatable portion associated therewith, the tubular members being releasably mounted upon the inflatable portion of each catheter, whereby upon inflation of the expandable, inflatable portion of each catheter, the tubular members are forced radially and outwardly into contact with the aorta and each other to remain secured thereto, whereby the tubes, secured to the tubular members, provide a bilateral passageway through the abdominal aortic aneurysm.

A further feature of the present invention is that each tube may be formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members may be embedded within a layer of a deformable and expandable plastic material. An additional feature of the present invention is that the expandable, inflatable portion of each catheter may extend along a portion of the length of each catheter a distance greater than the combined length of each tube and tubular member, whereby upon expansion and inflation of each expandable, inflatable portion of each catheter, each tubular member and its connected tube are simultaneously expanded.

The bilateral intra-aortic bypass graft for intraluminal delivery, and method and apparatus for repairing an abdominal aortic aneurysm of the present invention, when compared to previously proposed prior art grafts and methods and apparatus for repairing aneurysms, are believed to have the advantages of: a lower mortality rate; shortened recovery periods; not requiring suturing a graft to the aorta; utilizing the existing aortic wall and thrombosis therein to support and reinforce the aortic graft; being suitable for use with patients having other chronic illnesses; being less susceptible to kinking and/or twisting of the graft and permitting the use of a small diameter delivery system.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a partial cross-sectional view of an abdominal aortic aneurysm in the process of being repaired in accordance with the present invention;

FIG. 2 is partial cross-sectional view of an aorta, abdominal aortic aneurysm, and iliac aneurysm, in the process of being repaired in accordance with the present invention;

FIG. 3 is a partial cross-sectional view of a portion of the aorta of FIG. 1, illustrating a tubular member in the process of being expanded within the aorta;

FIG. 4 is a partial cross-sectional view of the aorta of FIG. 3, illustrating a tubular member being fully expanded;

FIG. 5 is a partial cross-sectional view of the abdominal aortic aneurysm of FIG. 2, illustrating the expansion of the bilateral intra-aortic bypass graft of the present invention;

FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 5;

FIG. 7 is a cross-sectional view taken along line 7-7 of FIG. 5; and

FIG. 8 is a cross-sectional view taken along line 8-8 of FIG. 5

FIG. 9 is a perspective view of a portion of a tube which forms a part of the bilateral intra-aortic bypass graft of the present invention;

FIG. 10A is a partial, perspective view of a portion of the bilateral intra-aortic bypass graft of the present invention;

FIG. 10B is a partial, perspective view of a portion of the bilateral intra-aortic bypass graft of the present invention;

FIG. 11 is a partial cross-sectional view of the aorta and abdominal aortic aneurysm of FIG. 2, illustrating the bilateral intra-aortic bypass graft of the present invention in place in the aorta and abdominal aneurysm;

FIG. 12 is a cross-sectional view taken along line 12-12 of FIG. 11;

FIG. 13 is a cross-sectional view taken along line 13-13 of FIG. 11;

FIG. 14 is a cross-sectional view taken along line 14-14 of FIG. 11;

FIG. 15 is a partial cross-sectional view of another embodiment of a bilateral intra-aortic bypass graft of the present invention;

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

In FIGS. 1, 2, 5 a bilateral intra-aortic bypass graft 150 for intraluminal delivery to repair an abdominal aortic aneurysm 151 in an aorta 152 having two iliac arteries 153L, 153R associated therewith is illustrated. Bilateral intra-aortic bypass graft 150, as well as other grafts to be hereinafter described, could also be utilized in the thoracic aorta, and can be used to repair thoracic aneurysms or thoracic dissecting aneurysms. Accordingly, use of the term "aortic aneurysm" in this specification and claims is intended to relate to and mean both abdominal aortic aneurysms and thoracic aneurysms. Aneurysm 151 includes areas of thrombosis 154, which are disposed against the interior wall surface 155 of aorta 152. Blood flows through the aorta in the direction of arrows 156. Associated with aorta 152, above aneurysm 151, are a plurality of renal arteries 157, in fluid communication with aorta 152.

With reference to FIGS. 1, 5, and 11, bypass graft 150 is seen to generally comprise: a first tube 160A having first and second ends 161A, 162A and wall surface 163A disposed between the two ends 161A, 162A, at least a portion of the tube 160A adapted to be disposed within the aneurysm 151; a second tube 160B having first and second ends 161B, 162B and a wall surface 163B disposed between the two ends 161B, 162B, at least a portion of the tube 160B adapted to be disposed within the aneurysm 151; and means for securing 165 the first ends 161A, 161B of the first and second tubes 160A, 160B to the aorta 152, the securing means including first and second tubular members 166A, 166B, each tubular member 166A, 166B having first and second ends 167A, 167B, 168A, 168B, the first tube 160A being connected to the first tubular member 166A, and the second tube 160B being connected to the second tubular member 166B. It should be noted that like reference numerals are utilized throughout this Detailed Description of the Invention, with different letter subscripts to identify components of the present invention which are identical in construction to each other, in that many components of the present invention are a mirror image of adjacent components.

Still with reference to FIGS. 1, 5, and 11, preferably, the tubular members 166A, 166B, of securing means 165 have a first diameter D (FIGS. 1 and 2), which permits intraluminal delivery of the tubular members 166A, 166B into the aorta 152. Upon the application from the interior of the tubular members 166A, 166B of a radially, outwardly extending force, as will be hereinafter described in greater detail, the tubular members 166A, 166B, have a second, expanded and deformed diameter D' (FIGS. 5 and 11), the second diameter D' being variable and dependent upon the amount of force applied to the tubular members 166A, 166B, whereby the tubular members 166A, 166B, may be expanded and deformed to secure the first ends 167A, 167B of the tubular members 166A, 166B to the aorta 152, and a bilateral passageway 200 (is formed within the abdominal aortic aneurysm 151) by passageways 191A, 191B extending through the tubular members 166 and tubes 160. Preferably, as seen in FIGS. 5 and 11, at least a portion of the first and second tubes 160A, 160B is in an abutting relationship, the abutting portions of the first and second tubes 160A, 160B, being generally disposed toward the upper ends 161A, 161B of tubes 160A, 160B, whereby bilateral intra-aortic bypass graft 150, after implantation within aorta 152 and aneurysm 151, generally has an inverted Y-shaped configuration, as illustrated in FIGS. 5 and 11. Additionally, after tubular members 166A, 166B have been expanded and have their second, expanded and deformed diameter D', at least a portion, and preferably all of, the first and second tubular members 166A, 166B, are in an abutting relationship, as seen in FIGS. 5 and 11.

With reference to FIG. 1, each tubular member 166A, 166B preferably has a smooth outer wall surface 169A, 169B disposed between its first and second ends 167A, 167B, 168A, 168B. Wall surfaces 169A, 169B, preferably have a substantially uniform thickness with a plurality of slots 173 formed therein, the slots 173 being disposed substantially parallel to the longitudinal axes of the tubular members 166A, 166B. It has been found that one type of tubular member 166, which is particularly useful as securing means 165 are the expandable intraluminal grafts disclosed in U.S. Patent No. 4,733,665, issued March 29, 1988; U.S. Patent No. 4,739,762, issued April 26, 1988; and U.S. Patent No. 4,776,337, issued October 11, 1988, all of the foregoing patents being in the name of Julio C. Palmaz, and assigned to Expandable Grafts Partnership. Each of these patents is incorporated herein by reference. Other tubular members 166 could be utilized as securing means 165, provided they have the ability to be controllably expanded and deformed from the first diameter D, which permits intraluminal delivery of securing means 165, to the second expanded and deformed diameter D', in order to secure the tubular members 166A, 166B, and their connected tubes 160A, 160B within aorta 152.

With reference to FIGS. 1 and 11, tubes 160A, 160B preferably have a generally, circular cross-sectional configuration, and tubes 160A, 160B made be made from a variety of materials, provided they have the requisite strength characteristics to be utilized as a bypass graft 150, as well as have the requisite compatibility with the human body in order to be used as a graft, or implant material, without being rejected by the patient's body. Examples for such materials are DACRON® and other polyester materials, TEFLON® (polytetrafluoroethylene), TEFLON® coated DACRON®, porous polyurethane, silicone,

expanded polytetrafluoroethylene, and expanded polyurethane. It is preferred that all of the foregoing materials be porous to allow for an intimal layer to form on the tubes 160. Additionally, tubes 160A, 160B can be made by the replamineform replicated life forms process, which is a method for fabricating uniformly microporous materials from marine skeletal structures. The foregoing described fabric materials can be knitted or woven, and can be warp or weft knitted. If the material is warp knitted, it may be provided with a velour, or towel like surface, which speeds up clotting of blood which contacts tubes 160A, 160B in order to increase the attachment, or integration, of tubes 160A, 160B to aorta 152, or to assist the integration of tubes 160A, 160B to the thrombosis 154. Tubes 160A, 160B can also be made of a bio-erodible , or degradable material, such as albumin or collagen or a collagen coated material. A tube 160 which is bio-erodible, would erode and dissolve, or degrade, over a period of time; however, it is believed that a layer of endothelium, or skin, will grow as the tubes 160A, 160B erode, the new layers of endothelium, or skin, provide a new, fluid impervious lining within aneurysm 151. In some procedures, it might be desirable to make tubes 160A, 160B of a fluid impervious material. Additionally, tubes 160A, 160B, as well securing means 165, or tubular members 166A, 166B, could have a coating of a biologically inert material, such as TEFLON® or porous polyurethane.

If any of the foregoing described materials are used for the manufacture of tubes 160A, 160B, the first ends 161A, 161B of tubes 160A, 160B may be connected to the second ends 168A, 168B of the tubular members 166A, 166B, as by a plurality of conventional sutures of polypropylene, DACRON®, or any other suitable material. Preferably, the ends 161A, 161B of tubes 160A, 160B overlap and cover the second ends 168A, 168B of tubular members 166A, 166B, such overlapping being approximately 50% of the length of tubular 166A, 166B. The first ends 161A, 161B of tubes 160A, 160B, which overlap the second ends 168A, 168B of tubular members 166A, 166B, are preferably constructed so that they are radially expandable, whereby the first ends 161A, 161B of tubes 160A, 160B can conform with the second, expanded and deformed diameter D' of the second ends 168A, 168B of the tubular members 166A, 166B. If tubes 160A, 160B are woven, the weave of the materials at its first ends 161A, 161B is looser, so that the desired radial expansion can be obtained. The intermediate portions 171A, 171B (FIG. 11) of tubes 160A, 160B disposed between first and second ends 161A, 161B, 162A, 162B thereof, are preferably not substantially radially expandable when tubes 160A, 160B are manufactured from the foregoing described fabric, or fabric like, materials.

With reference to FIGS. 9, 10A and 10B, another embodiment of tubes 160 of bypass graft 150 are illustrated. Each tube 160A, 160B is preferably formed of a plurality of expandable and deformable, tubular members 201. Each tubular member 201 has a longitudinal axis, with a plurality of tubular members 201 being aligned with their longitudinal axes being substantially parallel with each other, as illustrated by center line 202. Each tubular member 201 is detached, and spaced apart, from adjacent tubular members 201. Tubular members 201 are of the same construction of tubular members 166 previously described, however, the length of tubular members 201 and number of slots 173 extending along the length of each tubular member 201 may be varied depending upon the total length of tube 160. After the plurality of tubular members 201 have been aligned as illustrated in FIG. 9, with tubular members 201 being disposed with their first unexpanded diameter D which permits intraluminal delivery of the tubular members 201, the plurality of tubular members 201 are disposed in a suitable, conventional jig, die, or mold. The plurality of tubular members 201 are then embedded within a layer 202 of a deformable and expandable plastic material, such embedding being carried out through use of any conventional molding process. The plastic material may be silicone, polytetrafluoroethylene, expanded polytetrafluoroethylene, expanded polyurethane, or any other plastic material have the requisite strength characteristics to be utilized as a bypass graft, as well as have the requisite compatibility with the human body in order to be used as a graft, or implant material, without being rejected by the patient's body, as well as have the ability to expand as tubular members 201 are expanded, as will be hereinafter described, and be able to maintain the expanded configuration when tubular members 201 have a second, expanded and deformed diameter D' as illustrated in FIG. 10A.

The resulting tube 160, after the plurality of tubular members 201 have been embedded within the layer 202 of plastic material, is a tube 160 having a substantially smooth inner and outer surface 203, 204 formed by the layer 202 of plastic material in which tubular members 201 are embedded. It is believed that such tubes 160 will be substantially non-collapsible and not subject to kinking and/or twisting upon being implanted.

Tube 160 of FIG. 10A may be connected to the second end 168 of tubular member 168 in the manner previously described, such as by a plurality of conventional sutures; however, preferably the first and second tubular members 166A, 166B are connected to the first and second tubes 160A, 160B by embedding a portion of the second ends 168A, 168B of the first and second tubular members 160A, 160B in the plastic material 202 of the tube 160 to which tubular members 166A, 166B are to be connected, as illustrated in FIG. 10B. As seen in FIG. 10B, the upper end 167, or leading edge, of tubular member 168 is

exposed for direct contact with aorta 152 and its adjacent tubular member 166, as illustrated in FIGS. 10B, 5, and 11. The lower end 168, or trailing edge, of tubular member 166 being embedded within the layer 202 of plastic material, and spaced apart, and detached from the uppermost tubular member 201, as illustrated in FIG. 10A.

Still with reference to FIG. 9, alternatively each tubular member 201 may be spaced apart from adjacent tubular members 201 and connected by a single, flexible connector member 205, two such flexible connector members being illustrated, and the plurality of connected tubular members 201 are then embedded within the layer 202 of the deformable and plastic material. It is believed that one type of flexible connector member which may be particularly useful as connector members 205 are those illustrated in U.S. Patent Application Serial No. 174,246, filed March 28, 1988, and U.S. Patent Application Serial No. 657,296, filed February 19, 1991, both of these application being assigned to Expandable Grafts Partnership. Each of these applications is incorporated herein by reference. Other connector members 205 could be utilized, provided they have the ability to permit tubes 160 of FIGS. 10A and 10B, to be implanted as will be hereinafter described in greater detail, and to be intraluminally delivered to the aorta 152 which would require tube 160 to be flexible and capable of bending and flexing so as to negotiate through the curved veins, arteries, and/or body passageways toward the aorta 152.

With reference to FIG. 15, another embodiment of bilateral intra-aortic bypass graft 150 is illustrated. Graft 51' includes means for securing 192 the lower ends 162A, 162B of tubes 160A, 160B to the two iliac arteries 153. Securing means 192 preferably includes a third expandable and deformable tubular member 166A' connected to the second end 162 of the first tube 160A, and a fourth expandable and deformable, tubular member 166B' connected to the second end 162B of the second tube 160A. Preferably, third and fourth members 166A', 166B' are of the same type of construction as those used for securing means 165, or tubular members 166A, 166B. Third and fourth tubular members 166A', 166B' may be connected to the lower ends 162A, 162B of tubes 160A, 160B, as by means of sutures, previously described, when tubes 160A, 160B are of fabric, or similar construction, as previously described. Alternatively, if tubes 160A, 160B, have the construction as illustrated in FIGS. 9, 10A, and 10B, third and fourth tubular members 166A', 166B' may be also connected as by conventional sutures, as previously described, or preferably may be secured to the lower ends 162A, 162B of tubes 160A, 160B, by embedding a portion of the first ends 167A, 167B of tubular members 166A', 166B' in the deformable and expandable plastic material 202 disposed at the second ends 162A, 162B of tubes 160A, 160B as previously described in connection with FIG. 10B. As will be hereinafter described in further detail, securing means 192, or third or fourth tubular members 166A', 166B', may be expanded and deformed in the same manner as securing means 165 to force the third and fourth tubular members 166A', 166B' into contact with an iliac artery, 153L, 153R. Although the flow of pumped blood downwardly through aorta 152 and into iliac arteries 153L, 153R is believed to provide enough pressure to maintain bilateral passageways 191A, 191B, formed by tubes 160A, 160B, in their desired positions within iliac arteries 153L, 153R, as illustrated in FIGS. 11 and 15, there is a slight negative vacuum pressure component associated with the pumping pressure, whereby the securing means 192 might be required. Securing means 192 also serves to ensure no movement of passageways 191A, 191B, caused by a person's body movements.

With reference to FIGS. 1, 2, and 5, the method and apparatus for repairing an abdominal aortic aneurysm of the present invention will be described. Apparatus 180 for repairing an abdominal aortic aneurysm 151 generally comprises: first and second tubes 160A, 160B and first and second expandable and deformable tubular members 166A, 166B, tubular members 166 and tubes 160 being constructed as previously described; and two catheters 181A, 181B, each catheter have an expandable, inflatable portion 182A, 182B, or balloon 183 associated therewith and a nosepiece 184. The tubular members 166A. 166B are releasably mounted to the inflatable portion 182 of each catheter 181, in any suitable fashion, whereby upon inflation of the expandable, inflatable portion 182 of each catheter 181A, 181B, the tubular members 166A, 166B are forced radially outwardly into contact with the aorta 152 and with each other to remain secured to aorta 152, whereby the tubes 160A, 160B, secured to the tubular members 166A, 166B, provide a bilateral passageway 200, or bilateral passageways 191A, 191B (FIGS. 11 and 15) through the abdominal aortic aneurysm 151.

The apparatus 180 for repairing the abdominal aortic aneurysm 151 as illustrated in FIGS. 1 and 2, is in its configuration it would have for intraluminal delivery into aorta 152 and aneurysm 151. Preferably, the first tube 160A, tubular member 166A, and catheter 181A are intraluminally delivered through a first femoral artery; and the second tube 160B, tubular member 166B, and catheter 181B are intraluminally delivered through a second femoral artery and in turn each pass through an iliac artery 153L, 153R, as illustrated in FIG. 2. In the configuration shown in FIGS. 1 and 2, the tubular members 166A, 166B have their first unexpanded, undeformed diameter D. In FIG. 5, tubular members 166A, 166B, have been expanded and deformed into their second, expanded and deformed diameter D'. Expansion and deforma-

tion of tubular members 166A, 166B is controlled by the expansion of balloons 183 of catheters 181A, 181B in a conventional manner. When apparatus 180 is being intraluminally delivered, catheters 181A, 181B, tubular members 166A, 166B, and tubes 160A, 160B are preferably enclosed by conventional catheter sheathes 186A, 186B which are removed, as shown in FIG. 1, as apparatus 180 is disposed in its desired location within aorta 152.

If tubular members 166A, 166B, are utilized in connection with a fabric type tube 160, as previously described, balloon 183 of catheter 181 may have a length which extends from slightly beyond the first end 167 of tubular member 166, and to a position slightly beyond the second end 168 of tubular member 166. As illustrated in FIG. 5, if apparatus 180 includes tubes 160 constructed in a manner as described in FIGS. 9, 10A, and 10B, inflatable portion 182, or balloon 183 associated with each catheter 181 extends along a portion of the length of each catheter a distance greater than the combined length tube 160 and its associated tubular member 166, as illustrated in FIG. 5. Thus, upon expansion and inflation of each expandable and inflatable portion 182, or balloon 183, associated with each catheter 181, each tubular member 166A, 166B, is simultaneously expanded along with its connected tube 160A, 160B, including the plurality of tubular members 201 embedded within the layer 202 of plastic material of tubes 160A, 160B (FIGS. 9, 10A, 10B). Deflation of balloons 183 permits the withdrawal of catheters 181 and release of balloons 183 and catheters 181 from bypass graft 150 after graft 150 has been disposed in the configuration illustrated in FIG. 5. When tubes 160 are utilized of the construction illustrated in FIGS. 9, 10A, 10B, as shown in FIG. 5, the resulting bilateral passageway 191 formed in aorta 152 and aneurysm 151 is believed to be substantially non-collapsible , because of the presence of the plurality of tubular members 201 embedded within tubes 160A, 160B.

When implanting a bypass graft 150 of the construction illustrated in FIG. 15, first, second, third, and fourth tubular members 166A, 166B, 166A', 166B' may be simultaneously expanded and deformed into the expanded configuration illustrated in FIG. 15, as by use of the catheters 182 illustrated in FIG. 5, along with tubes 160A, 160B.

As illustrated in FIGS. 1, 2, 5, and 6, tubular members 166A, 166B, are initially disposed within aorta 152 substantially even and on the same level as each other, at which time sheathes 186 are removed and balloons 183A, 183B are simultaneously expanded as illustrated in FIGS. 5 and 6, until tubular members 166A, 166B are in an abutting relationship with each other and against aorta 150. Upon final inflation and expansion of the balloons 183A, 183B to force tubular members 166A, 166B into their final configuration illustrated in FIGS. 11 and 12, the abutting portions 210A, 210B of tubular members 166A, 166B, are flattened against each other into the configuration shown in FIG. 12, whereby the initially present gaps 211 (FIG. 6) between adjacent tubular members 166A, 166B, are closed off and removed.

FIGS. 13 and 14 illustrate bypass graft 150 after it has been implanted for a period of time, whereby the aneurysm 151 has thrombosed about tubes 160A, 160B and into contact therewith, and bilateral passageways 191A, 191B are thus disposed within aneurysm 151.

With reference to FIGS. 3 and 4, an alternative method for repairing an abdominal aortic aneurysm in an aorta 152 is illustrated. In this embodiment, bilateral intra-aortic bypass graft 150 includes a fifth expandable and deformable tubular member 166C of the same construction of the first through fourth tubular members 166A, 166B, 166A', 166B' as previously described. Prior to the intraluminal delivery of tubular members 166A, 166B, and tubes 160A, 160B as previously described in connection with FIGS. 1, 2, and 5, the fifth tubular member 166C is intraluminally delivered by a third catheter 181' and expanded from its first diameter D" to its second, expanded and deformed diameter D"', as illustrated in FIG. 4, to secure the fifth tubular member 166C within the aorta 152. After the fifth expandable tubular member 166C has been implanted within aorta 152, as shown in dotted lines in FIG. 1, the remaining elements of bypass graft 150 are implanted within aorta 152 and aneurysm 151 as previously described in connection with FIGS. 1, 2, and 5. Upon expansion of first and second tubular members 166A, 166B, as previously described, those tubular members 166A, 166B, will be in abutting relationship with each other, as illustrated in FIG. 12, and will also be secured within aorta 152, via their expansion and deformation, into contact with fifth tubular member 166C which is secured in aorta 152.

It is believed that the use of fifth tubular member 166C will provide adequate anchorage for the tubular members 166A, 166B of bypass graft 150, and equalize forces exerted upon aorta 152 by the expansion of tubular members 166A, 166B. Fifth tubular member 166C has a final expanded diameter D"' which is approximately twice the size of the expanded diameter D' of tubular members 166A, 166B. Because fifth tubular member 166C does not have a tube 160 attached thereto, its delivery system, or catheter 181' and sheath 186' can be smaller, and they can be intraluminally delivered without any of the previously described disadvantage as sociated with prior art aortic grafts, having a large diameter tube connected thereto.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. For example, the ex-

pandable, inflatable portions of the catheters could be a plurality of hydraulically actuated rigid members disposed on a catheter or a plurality of balloons could be utilized to expand the securing means. Additionally, the wall surfaces of the tubular members could be formed by a plurality of wires having a smooth exterior surface. The tubes could also be used individually as grafts for other body passageways. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

Claims

1. A bilateral intra-aortic bypass graft for intraluminal delivery to repair an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith, comprising:

   a first tube having first and second ends and a wall surface disposed between the two ends, at least a portion of the first tube adapted to be disposed within the abdominal aortic aneurysm;

   a second tube having first and second ends and a wall surface disposed between the two ends, at least a portion of the second tube adapted to be disposed within the abdominal aortic aneurysm; and

   means for securing the first ends of the first and second tubes to the aorta, the securing means including first and second tubular members, each tubular member having first and second ends, the first tube being connected to the first tubular member and the second tube being connected to the second tubular member, the tubular members having a first diameter which permits intraluminal delivery of the tubular members and tubes into the aorta and the tubular members having a second, expanded and deformed diameter, with at least a portion of the first and second tubular members in an abutting relationship, upon the application from the interior of the tubular members of a radially, outwardly extending force, the second diameter being variable and dependent upon the amount of force applied to the tubular member, whereby the tubular members may be expanded and deformed to secure the first ends of the tubular members to the aorta and a bilateral passageway is formed within the abdominal aortic aneurysm.

2. The bilateral intra-aortic bypass graft of claim 1, wherein at least a portion of the first and second tubes are in an abutting relationship with each other when the first and second tubular members have their second, expanded and deformed diameter.

3. The bilateral intra-aortic bypass graft of claim 1 or 2, wherein each tubular member has a smooth outer wall surface disposed between its first and second ends, the wall surfaces having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the tubular members, a first end of a tube being secured to a second end of a tubular member.

4. The bilateral intra-aortic bypass graft of any preceding claim, wherein a biologically inert coating is disposed on the tubes.

5. The bilateral intra-aortic bypass graft of any preceding claim, wherein the tubes are made of material which is impervious to the flow of fluid.

6. The bilateral intra-aortic bypass graft of any preceding claim, wherein the tubes are made of a material which is bio-erodible.

7. The bilateral intra-aortic bypass graft of any preceding claim, wherein a third expandable and deformable, tubular member is connected to the second end of the first tube; a fourth expandable and deformable, tubular member is connected to the second end of the second tube; and the third and fourth tubular members are expanded and deformed to force the third and fourth tubular members radially outwardly into contact with an iliac artery.

8. The bilateral intra-aortic bypass graft of any preceding claim, wherein each tube is formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members are embedded within a layer of a deformable and expandable plastic material.

9. The bilateral intra-aortic bypass graft of claim 8, wherein the plastic material is silicone.

10. The bilateral intra-aortic bypass graft of claim 8, wherein the plastic material is polytetrafluoroethylene.

11. The bilateral intra-aortic bypass graft of claim 10, wherein the plastic material is expanded polytetrafluoroethylene.

12. The bilateral intra-aortic bypass graft of claim 8, wherein the plastic material is expanded polyur-

ethane.

13. The bilateral intra-aortic bypass graft of claim 8, wherein the first and second tubular members are connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is to be connected.

14. The bilateral intra-aortic bypass graft of claim 1, including a fifth expandable and deformable tubular member, wherein:
(a) after the fifth expandable and deformable, tubular member has been intraluminally delivered and expanded and deformed to force the fifth tubular member radially outwardly into contact with the aorta to secure the fifth tubular member within the aorta; and
(b) after the expansion and deformation of the first and second tubular members, the first and second tubular members are disposed within the fifth expandable tubular member in an abutting relationship with each other and with the fifth expandable tubular member, whereby the first and second tubular members may be secured within the aorta and within the fifth tubular member.

15. The bilateral intra-aortic bypass graft of claim 14, wherein each tube is formed of a plurality of expandable and deformable tubular members, each tubular member having a longitudinal axis with the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other; each tubular member being spaced apart from adjacent tubular members with a single, flexible connector member being disposed between adjacent tubular members; and the plurality of tubular members are embedded within a layer of a deformable and expandable plastic material.

16. The bilateral intra-aortic bypass graft of claim 15, wherein the plastic material is silicone.

17. The bilateral intra-aortic bypass graft of claim 15, wherein the plastic material is polytetrafluoroethylene.

18. The bilateral intra-aortic bypass graft of claim 17, wherein the plastic material is expanded polytetrafluoroethylene.

19. The bilateral intra-aortic bypass graft of claim 15, wherein the plastic material is expanded polyurethane.

20. The bilateral intra-aortic bypass graft of claim 15, wherein the first and second tubular members are connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is to be connected.

21. An apparatus for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith, comprising:
(a) first and second tubes, each tube having first and second ends and a wall surface disposed between the two ends;
(b) first and second expandable and deformable tubular members, each expandable and deformable tubular member, having first and second ends and a smooth outer wall surface disposed between the first and second ends, the first end of a tube being secured to a second end of a tubular member, the expansion and deformation of the tubular members being controllable; and
(c) two catheters, each catheter having an expandable, inflatable portion associated therewith, the tubular embers being releasably mounted upon the inflatable portions of each catheter, whereby upon inflation of the expandable, inflatable portion of each catheter, the tubular members are forced radially outwardly into contact with the aorta and each other to remain secured thereto, whereby the tubes, secured to the tubular members, provide a bilateral passageway through the abdominal aortic aneurysm.

22. The apparatus of claim 21, wherein each tube is formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members are embedded within a layer of a deformable and expandable plastic material.

23. The apparatus of claim 22, wherein the expandable, inflatable portion of each catheter extends along a portion of the length of each catheter for a distance greater than the combined length of each tube and tubular member, whereby upon expansion and inflation of each expandable, inflatable portion of each catheter, each tubular member and its connected tube are simultaneously expanded.

24. The apparatus of claim 21, wherein each tube is formed of a plurality of expandable and deformable tubular members, each tubular member having a longitudinal axis with the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other; each tubular member being spaced apart from adjacent tubular members with a single, flexible connector member being disposed between adjacent tubular members; and the plurality of tubular members are embedded within a layer of a deformable and expandable plastic material.

25. The apparatus of claim 24 , wherein the expandable, inflatable portion of each catheter extends along a portion of the length of each catheter for a distance greater than the combined length of each tube and tubular member, whereby upon expansion and inflation of each expandable, inflatable portion of each catheter, each tubular member and its connected tube are simultaneously expanded.

26. A graft for intraluminal delivery into a body passageway comprising:

an elongate tube having first and second ends and formed of a plurality of expandable and deformable first tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached and spaced apart form adjacent tubular members, and the plurality of tubular members being embedded within a layer of a deformable and expandable plastic material; and

means for securing the first end of the tube within a body passageway, the securing means being a second expandable and deformable tubular member having first and second ends, the first end of the tube being connected to the second end of the second tubular member, the second tubular member having a first diameter which permits intraluminal delivery of the tubular member and tube into the body passageway and the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, the second diameter being variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to secure the first end of the tubular member within the body passageway.

27. The graft of claim 26, wherein the second tubular member is connected to the tube by embedding a portion of the second end of the second tubular member in the deformable and expandable plastic material of the tube to which it is connected.

28. The graft of claim 26, wherein the plastic material is silicone.

29. The graft of claim 26, wherein the plastic material is polytetrafluoroethylene.

30. The graft of claim 26 , wherein the plastic material is expanded polytetrafluoroethylene.

31. The graft of claim 26, wherein the plastic material is expanded polyurethane.

32. The graft of claim 26 , wherein a single flexible connector member is disposed between the adjacent tubular members of the plurality of first tubular members which form the tube.

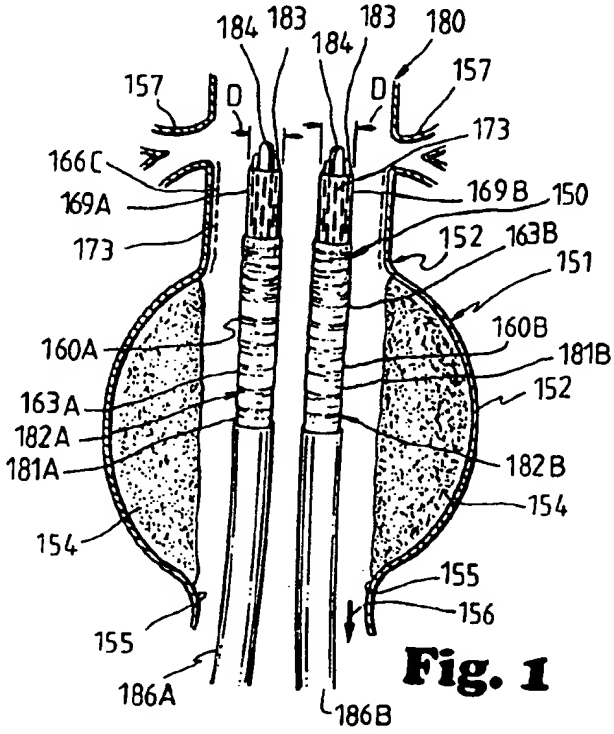

Fig. 1

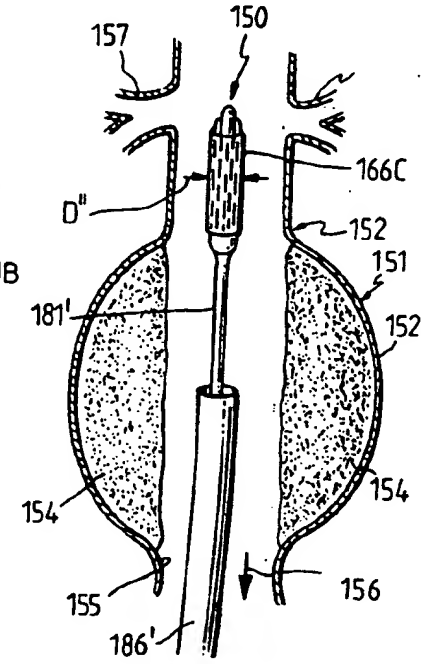

Fig. 3

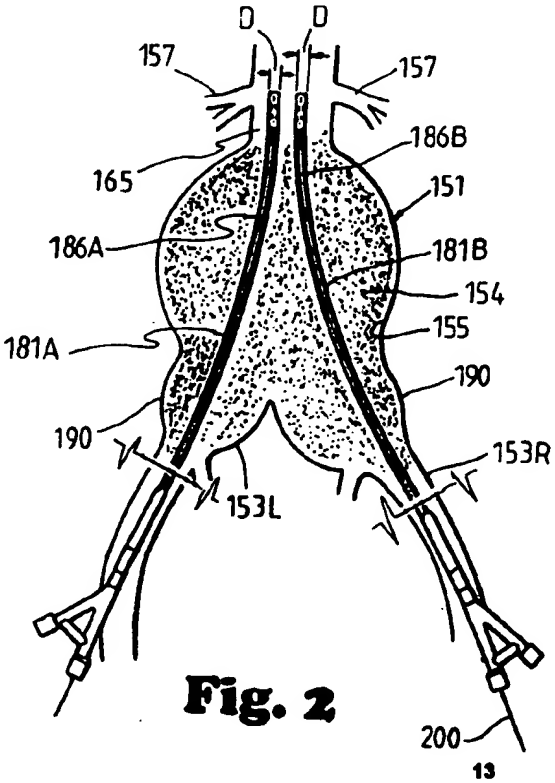

Fig. 2

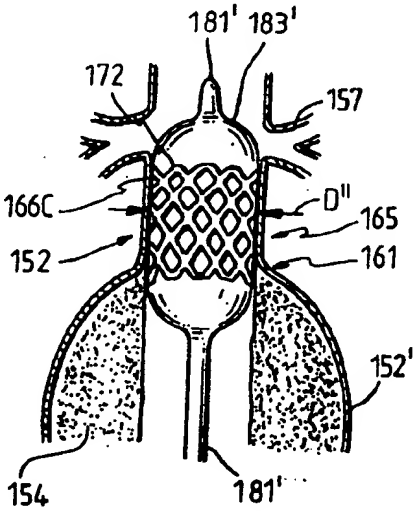

Fig. 4

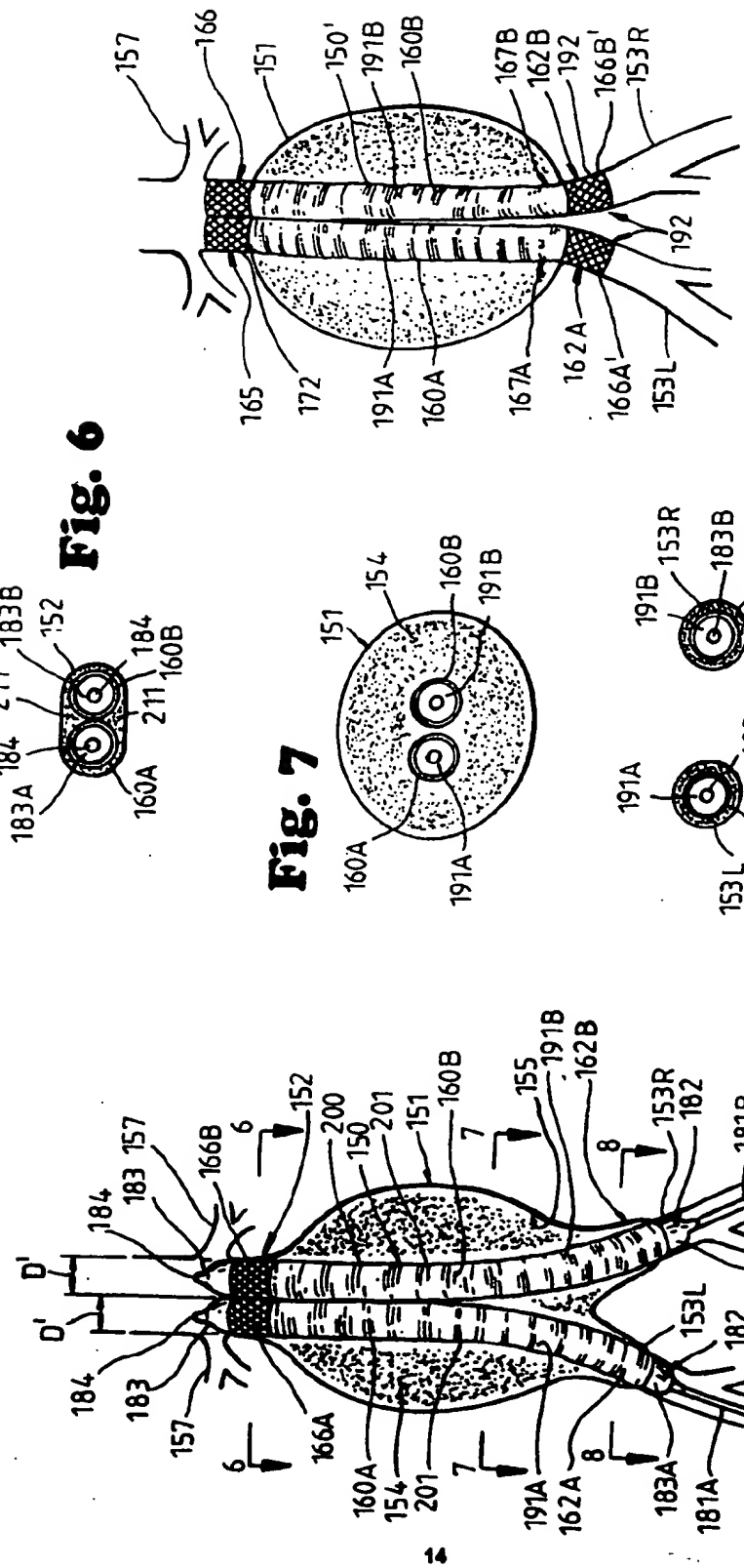

Fig. 5

Fig. 6

Fig. 7

Fig. 8

Fig. 15

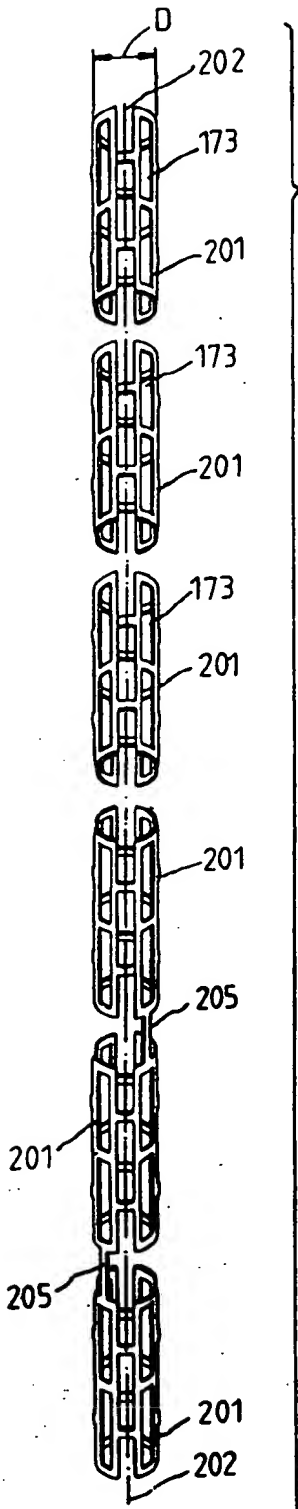

Fig. 9

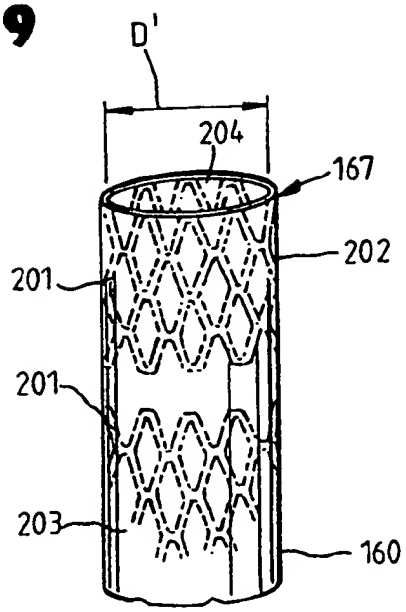

Fig. 10A

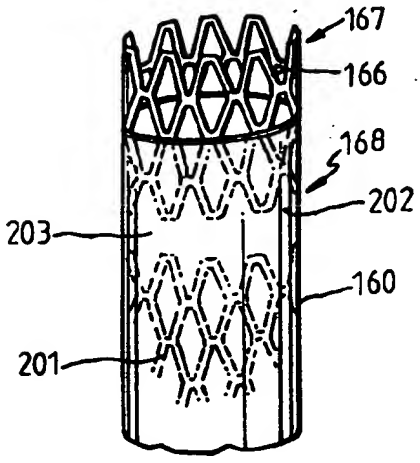

Fig. 10B

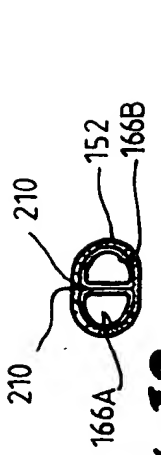

Fig. 12

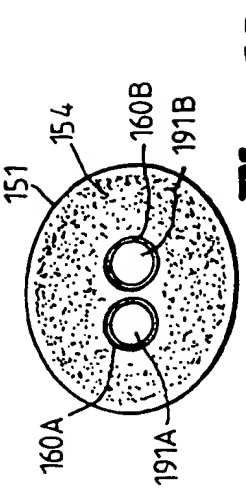

Fig. 13

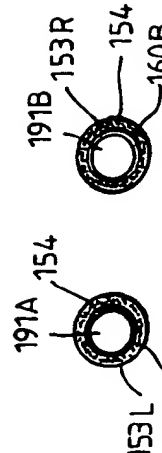

Fig. 14

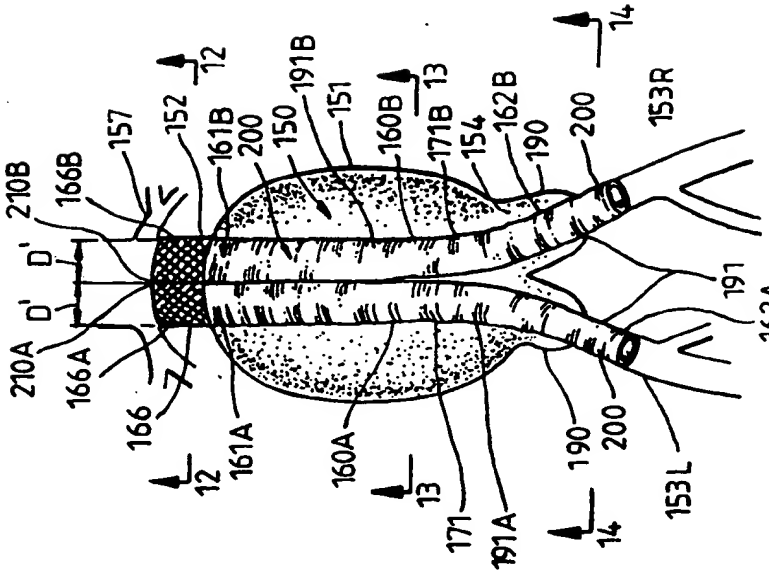

Fig. 11

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 0047

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	EP-A-0 461 791 (BARONE ET AL.) * column 8, line 12 - column 9, line 2 * * claims 1-9; figures *	1,3-32	A61F2/06
Y	EP-A-0 364 787 (EXPANDABLE GRAFTS PARTNERSHIP) * column 12, line 23 - column 14, line 9; figures *	1,3-32	
A	US-A-3 657 744 (ERSEK) * claim 1; figure 1 *	1	
A	US-A-4 562 596 (KORNBERG)	-	
P,A	EP-A-0 479 557 (BARONE ET AL.) * abstract * * figure 1 *	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61F
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	23 FEBRUARY 1993	GODOT T.

CATEGORY OF CITED DOCUMENTS

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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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